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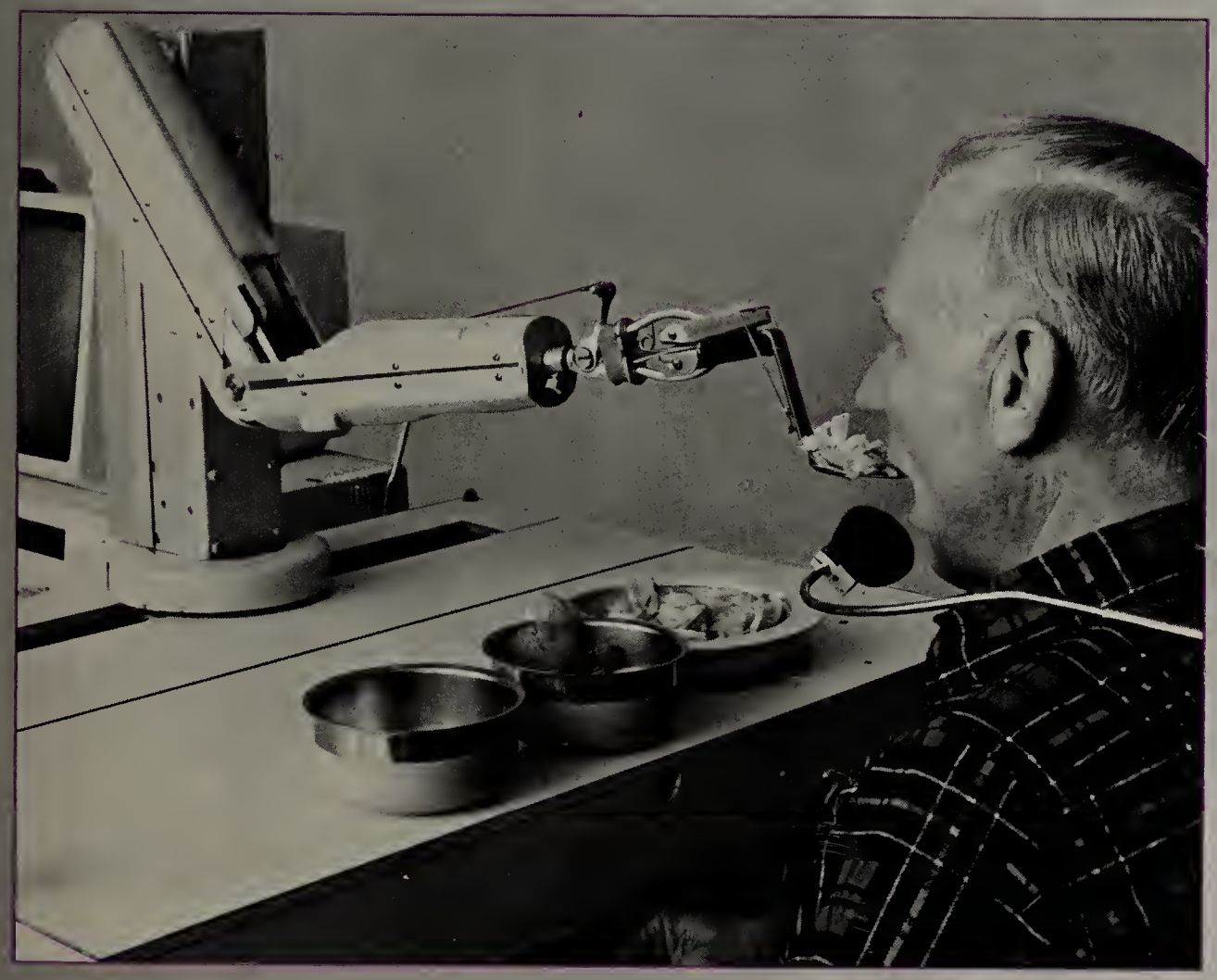

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Guidelines for Submitting Progress Reports

We welcome contributions to the annual *Rehabilitation R&D Progress Reports*. A comprehensive review of research and progress is essential, and we do not want significant work omitted.

Progress reports are meant to facilitate access to sources of information, formal or informal, about scientific research and engineering developments, both completed or ongoing. The reports are not treated as short research papers, they are not refereed, and their contents are solely the statements of the investigators.

Reports intended for the 1986 issue must be received at the Office of Technology Transfer (address below) no later than July 1, 1986. The text should follow the format of reports in the 1985 issue and contain a brief summary of the purpose, progress to date, and preliminary findings and/or results since the last report. If a project is not completed, a brief comment on future plans or goals is appropriate. The entire report should not exceed 600 words.

For completed projects, only a brief final summary should be supplied to *Rehabilitation R&D Progress Reports*. Detailed scientific findings should be submitted to the *Journal of Rehabilitation and Research Development* or other appropriate scientific journals for publication.

Please give bibliographic references for publications and/or patent information as applicable for all completed projects that were included in *Rehabilitation R&D Progress Reports — 1983, 1984*, and *1985*.

Follow these publication requirements:

1) Type letter-quality, double-spaced on 8½ × 11 inch paper, numbering the pages visibly.
2) If possible, send with your hard copy report the same material on a 5¼ inch floppy disk (non-returnable) with text in IBM PC format — generic ASCII text. If the IBM PC format is unavailable to you, label the disk you send for computer brand name and name and version of software. Progress reports may also be transmitted to this office by telephone via modem. To make such arrangements call the Technology Transfer Information Exchange System operator at (202) 745-8480.
3) Include investigator(s) name(s) with highest degree, position, organization, and location (full address and zip code of principal investigator).
4) Clearly indicate on the first page the source(s) of funding for the work described in the report and the location of the actual research activity.

Address contributions to: Editor
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Washington, D.C. 20422

Progress reports and information on publications/patents relating to completed projects must be received by July 1, 1986 in order to be included in the 1986 issue.

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Rehabilitation R&D Progress Reports

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Editor's note

The *Rehabilitation R&D Progress Reports* is an annual compilation of ongoing work in the field of rehabilitation research and engineering both in this country and abroad. Our goal has been to achieve increasingly comprehensive coverage in each annual edition. This edition represents a substantial increase in the number of progress reports included.

Now that *Rehabilitation R&D Progress Reports* is in its third year of publication, each issue not only presents a view of current work, but also allows readers to study the progress of selected research over a two or more year period. In the 1986 issue, we plan to cite publications and patents that have resulted from the research reported in earlier issues. The dissemination of research findings will thus be facilitated since readers will readily be able to obtain the results of completed research.

A revised format in the 1985 issue enhances readability and allows readers to make notes and use it more easily as a working tool. An additional category has been included: Head Trauma and Stroke.

The sponsor index lists participating agencies and organizations along with the research projects each has funded over the past year. Contributors are listed alphabetically with the page numbers of their reports in the final section of the book.

The deadline for submitting progress reports for the next issue is July 1, 1986. Guidelines for content and format are on page ii.

On the cover: The **VA Wheelchair Control and Robot Arm/Work Table System** for high spinal cord injured persons, currently undergoing clinical evaluation and engineering refinement at selected research facilities. Recent improvements to the system include a self-adjusting chin controller of the wheelchair and a simultaneous multiaxial motion feature for the Robot Arm. A report on the evaluation progress, including user experiences, is on page 147.

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375 Regency Park Centre for Young Disabled (Australia)

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376 Royal National Institute for the Blind (England)
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378 U.S. Social Security Administration
378 University of Strathclyde, Bioengineering Unit, Wolfson Centre (Scotland)
378 Veterans Administration
378 Veterans Administration, Department of Medicine and Surgery, Rehabilitation Research and Development Service
387 VA Hospital, Little Rock, AR
387 VA Medical Center, Rehabilitation Medicine Service, Long Beach, CA
387 VA Medical Center, St. Cloud, MN
387 VA Medical Center, Manchester, NH
388 VA Medical Center and State University of New York at Albany
388 Wichita Rehabilitation Engineering Center

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Rehabilitation R&D Progress Reports 1985

I. Amputations and Limb Prostheses

A. General

Comprehensive Management of Upper and Lower Extremity Amputation

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The goal of this project was four-fold: 1) to complete our work using intradermal Xenon-133 for amputation level selection; 2) to finalize techniques for building inexpensive, rapidly fabricated, temporary, or throwaway prostheses; 3) to study follow-up information regarding the role of immediate postsurgical fitting for upper extremity amputation; and, 4) to define the role of an elective amputation with early prosthetic fitting for patients with neurologic dysfunction.

Progress — Intradermal Xenon-133 amputation level selection was performed in the Nuclear Medicine Department using a Gamma camera interfaced with a microcomputer. Simultaneous two-point injection was performed in order to provide comparison for detection of injection error. All isotope wash out curves were computer analyzed for statistician validity. Besides accuracy of the measurements, an additional advantage of the Gamma camera technique was that multiple amputation levels could be checked simultaneously.

Lower Extremity — For all below-knee amputees, immediate postsurgical prosthetic fitting (IPSF) included touchdown weightbearing the morning after surgery. The patients then progressed during the next 7 to 14 days to full weightbearing and they were usually discharged from the hospital the third week after amputation. Partial foot and high level amputees had rigid dressings placed at the time of surgery; however, touchdown weightbearing and ambulation were postponed until wound healing had occurred (7 to 10 days). At the time of hospital discharge all lower extremity amputees were fitted with a lightweight, throwaway prosthesis that was changed as required to maintain prosthetic fit. No patient was referred for a permanent prosthesis earlier than six months after amputation in order to allow time for stump maturity.

Upper Extremity — All upper extremity amputee patients were fitted with IPSF standard conventional body-powered prosthetic devices. Upper extremity rehabilitation began the day after surgery, and included all Activities of Daily Living (ADL) skills. The prostheses were changed as required to maintain function (every 3 to 5 days). Harnessing was individually adapted in each patient to maximize prosthetic function. All patients were discharged with standard body-powered conventional prosthetic devices an average of 14 to 21 days after surgery. Only those patients who continued to use their body-powered prosthetic devices were evaluated for externally powered components (mean: 3 months).

Results — 1) Intradermal Xenon-133 skin blood flow had greater than 95 percent accuracy for the prediction of healing of major forefoot, below-knee, and above-knee amputations; however, intradermal Xenon-133 had less reliability for the prediction of healing of toe and distal forefoot amputations (80 percent).

2) We have previously reported that there is a 30-day grace period for early/rapid prosthetic fitting following upper extremity amputation, after which time the success rates of rehabilitation declined dramatically. Further analysis of patients treated in our program, as well as analysis of patients treated in our local community during the past year, reaffirm the 30-day rule. In addition, it would seem from a review of data from other centers that there are two breaks in the rehabilitation curve with respect to the success of prosthetic fitting after upper extremity amputation, one occurring at 30 days and one occurring at three months. The likelihood of long-term prosthetic success, if an upper extremity amputee is fitted more than three months after amputation, seems to be small.

3) We have concluded that there is a role for elective amputation, shoulder fusion, and prosthetic fitting for patients who have neurologic dysfunction due to brachial plexus injury. We also have concluded that this modality does not have value for patients with neurologic dysfunction due to stroke.

4) Our techniques for fabrication of temporary throwaway prostheses from inexpensive materials have been previously described. The techniques have been extremely effective in bridging the prosthetic/monetary gap between the last post-surgical fitting and the first definitive or permanent prosthesis.

Future Plans — Our present program has been divided into clinical and research counterparts. The research program will become a collaborative effort between the College of Engineering at the University of Arizona and the Tucson VA Medical Center. The direction of that program will involve comparison studies on amputation level selection and investigations into the value of educational programs in preventing amputation in high risk patients, especially those with diabetes mellitus. The clinical program will continue to be involved in early and rapid prosthetic fitting for both upper and lower extremity amputees.

A Bibliographic Database and Information Retrieval System to Prosthetics and Orthotics

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Sponsor: Chief Scientist Office, Committee for Research on Equipment for the Disabled, Scottish Home and Health Department

Purpose — A database of bibliographical references is being established in the subject area of prosthetics and orthotics. The database will be utilized to offer a variety of regular and selective information services to health care professionals. An information officer and clerical assistant concern themselves with the day-to-day running of the project including data entry, retrieval, and the handling of requests.

Progress — The database is under development on the university triple VAX 11/782 cluster utilizing the Famulus software process. Bibliographical references to English language journal articles, conference proceedings, technical reports, and

monographs concerning scientific material are being utilized. The subject area will be prosthetics and orthotics, including seating, wheelchairs, and other aids for the physically disabled. A thesaurus of terms is planned to facilitate flexible classification and retrieval of information.

The system has been conceived to meet the needs of rehabilitation professionals and established with a view to offering a broad service. Some 6000 records have been created in work so far. Funding has been secured for three years in which time the system will be promoted widely and its effectiveness assessed with a view to securing long-term funding.

Flexible Sockets for Prostheses

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Sponsor: Department of Veterans' Affairs

Purpose — Silicone liners are investigated for both upper and lower limb prostheses. The major indication seems to be for upper limbs, especially for a better containment of the electrodes for myoelectric hands.

A comparative study is progressing between the ISNY and the ISPO above-knee transparent flexible sockets. High acceptance rate by the patients is being recorded. The study continues to assess durability and reactions of the stump in hot weather, with the view of introducing this type of socket on the D.V.A. Free Limb Scheme.

Determination of Causes of Phantom Limb Pain

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Purpose — We have surveyed over 6,300 amputee veterans and established that a minimum of 80 percent experience significant, frequently debilitating, episodes of phantom limb pain at least several times per year. Responses from this survey and from a survey of physicians treating phantom pain showed that treatment success is almost nonexistent except in rare cases where the specific referral mechanism is identified and the cause corrected. Our recent physiological studies have demonstrated relationships between burning phantom limb pain and stump blood flow as well as between sharp/shooting phantom pain and stump microspasms.

Progress — We are carrying out a three-part study to demonstrate the actual mechanisms underlying phantom pain that should provide the information necessary to develop effective treatments for it:

1) Survey of factors initiating and altering the intensity of phantom limb pain. We will send a survey to 6,000 veteran amputees in which we will elicit detailed information about these factors and their effects. This will provide a firm basis for determining which physiological mechanisms are related to phantom pain. We have sent out the trial survey (1,000 letters) and have already proven that there is no relationship between respondents' need to control what happens (locus of control) and whether or not they are aware of what causes their phantom pain.

2) Objective log of factors changing with changes in intensity of phantom pain. We are requesting respondents who are able to identify factors clearly effecting their pain to make daily logs of changes in those factors and the intensity of their phantom pain for one year. Sixty respondents from the trial survey are participating in this phase of the research. It is already clear that changes in humidity have a very real effect on phantom pain intensity for some but not for others. We are still evaluating the data to determine whether there is a difference between humidity effects and description of phantom pain. When we carry out the main survey, 20 respondents for each of the major factors identified will be asked to participate in this part of the study. Experience indicates we can expect 50 percent compliance over one year of keeping a log. This will permit analysis of temporal and rhythmic alterations as well as complex interrelationships between several factors that would not be obtainable in other ways.

3) Physiological evaluation of subjects with phantom limb pain. Groups of 12 amputee subjects having each of the nine major descriptive types of phantom pain we have identified are being recruited for recording in our Psychophysiology Laboratory twice while pain free and twice while experiencing phantom limb pain. Near surface blood flow in the stump and paired extremity are being measured using a TV videothermography system. Muscle tension in the major stump, the paired intact limb, and the low back are being measured with standard noninvasive surface electromyographic techniques. Blood pressure is being measured in all four limbs using an automatic sphigmomanometer. To date, we have recruited 16 amputees for this portion of the study. All are showing a relationship between changes in phantom pain intensity and at least one of the above physiological parameters.

Morphological and Clinical Studies of Microwounds in Ischemic Human Tissue

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The purpose of this project is to study in a systematic fashion morphological and clinical features of small standardized wounds created on the lower extremities of patients with severe peripheral vascular disease (PVD) necessitating amputation.

Progress — The wounds are created with a Simplate II bleeding time device under sterile conditions at locations immediately distal to the planned site of amputation and at a variety of clinically and biologically relevant time periods for the study of wound healing. Wounds are examined clinically immediately prior to amputation and then excised from the amputation speciman and fixed for morphological studies. When normal control subjects are used, standard skin punch biopsies are used to remove the microwounds.

Standard techniques are used for tissue fixation, sectioning, and evaluation of all samples by light microscopy and of selected samples by transmission and scanning electron microscopy. Morphological events of healing are then compared with forearm wounds of young adults from previous studies and leg microwounds from age-matched controls. Transcutaneous oxygen tension ($TcPO^2$)

at the site of microwounds, the clinical appearance of the microwounds, the outcome of the amputation, and a variety of risk factors for PVD, such as smoking, diabetes, and hypertension also are correlated with microwound healing.

Preliminary Results — During the past year, seven additional patients have had microwounds created prior to amputation and ten normal elderly subjects have had microwounds created and biopsied to serve as age-matched controls for the amputation patients. In addition to the morphological studies of the normal and abnormal wound tissue, immunohistochemical studies also have been performed on all normal and selected abnormal wounds. The normal subjects have wound repair which is clearly more advanced than patients undergoing amputation but it is significantly more delayed than the normal young adult forearm microwounds. The observations of normal elderly leg wound healing are unique and will provide an important point of reference for both past and future investigators regarding wound healing in diabetic and ischemic patients.

B. Lower Limb

1. General

Computer-Aided Alignment of Lower Limb Prosthesis and "Expert" Systems

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — There are two specific objectives to this project: 1) obtain quantitative information concerning relationships between alignment variables and gait characteristics typically associated with these variables in the alignment protocol; and 2) develop an expert system for alignment of below-knee prosthesis that has as its knowledge base a formalization of the rules for prosthetic alignment which have been derived from expert prosthetists' knowledge, judgment and experience. The development of the expert system is contingent upon transforming and formalizing the rules utilized in the alignment protocol into a quantitative, objective domain. Our efforts during the first year of our grant period have been focused on developing objective measurement tools that will be used initially during the alignment process to establish a pre-determined alignment state and evaluate the gait characteristics of several amputees at this particular alignment state.

Progress — Near the beginning of the grant period, we received a major component of our measurement system, the CODA-3 Movement Monitoring Instrument. We have successfully interfaced our LSI 11/23-based computer to the CODA-3 (requiring both hardware and software). In addition, we have fabricated

a rigid, portable support structure for the CODA instrument. Using this system, we are able to measure position coordinates of landmarks (which may be attached to a prosthetic socket or foot) to within ±0.2mm for measurements in a plane perpendicular to the CODA's field of view and at the same distance (3.2 Meters), to within ±0.9mm in the longitudinal direction. For angular measurements of a line formed between two markers spaced 90mm apart (at this same distance) position inaccuracies result in a measured standard deviation of ±0.05 degrees. Accuracy can be further improved by increasing the spacing between markers. Software has been written to generate a user-interactive nulling display through which prosthetic angular orientation can be set in space to within two standard deviations of the system accuracy (0.05 degrees for the above case). These measurement techniques will be next utilized to allow the alignment state of the prosthesis to be set for three positions and three orientation degrees-of-freedom. This will be achieved using a user-interactive display which allows simultaneous nulling of all six alignment degrees-of-freedom to a target state.

Progress concerning the development of measurement tools for establishing amputee walking characteristics has resulted in completion of software allowing measurement and storage of landmark position coordinates and the status of several switches at 300Hz for up to 12 seconds. Software has been completed which allows this data to be transformed into another reference frame which has an inertial orientation with an arbitrary origin. Software to allow line drawings (stick-figures) to be generated in real-time on a graphics monitor and subsequently printed or plotted has also been completed.

The Development of a Computer-Aided Measurement System for Prosthetic Applications

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Sponsor: Chief Scientist Office, Committee for Research on Equipment for the Disabled, Scottish Home and Health Department

Purpose — A computer-aided measurement system is being developed to permit the identification and measurement of selected stump dimensions of lower limb amputees. The system aims to be compatible with processes of automated prosthesis design and manufacture under development by collaborators at the Bioengineering Centre, University College London (UCL), England and the Medical Engineering Resource Unit (MERU), University of British Columbia, Canada. The system is intended to function in a complementary manner to the computer-aided socket design (CASD) system devised by MERU. The measurement system functions as electronic calipers utilizing a video camera to view the stump, hardware to capture an image of the stump, and software to furnish the required measurements.

Progress — The measurement system does not contact the amputee; the stump is viewed by a monochrome video camera interfaced with a commercially available image processor and controlled by an IBM PC-AT computer system utilizing Pascal software. In its current state of development lighting of the stump is arranged to give a silhouette image which may be acquired under software control in 1/25th of a second, 768 × 576 pixel resolution and in 128 grey levels. Images are loaded into the IMByte frame buffer for processing and then image processing

principles are used to identify the stump.

The prototype measurement system is now operational and future work will be directed toward clinical trials of the system when used in conjunction with the CASD software package and methods of automated prosthesis manufacture being produced by UCL. The feasibility of extension of the system to total shape sensing is being investigated.

Biomechanical Evaluation of Prosthetic Feet

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Sponsor: University of Strathclyde

Purpose — The biomechanical evaluation of SACH and uniaxial feet outlined in the VA Rehabilitation R & D Progress Reports — 1983 has been published. During the investigations it became apparent that more information could be obtained if the local action of the foot could be examined in greater detail. It was therefore decided to continue the project by first considering the uniaxial type of foot.

The aim of this work is to obtain a better understanding of the function of prosthetic feet and to obtain data which would allow criteria for improved designs to be established.

Progress — The kinematics and kinetics of the foot/ankle complex are being investigated by strain gauging the ankle adaptor and recording the angular motion by means of a specially designed flexible goniometer. A series of membrane switches attached along the length of the plantar surface of the foot provide detailed information of its movements and temporal parameters.

Tests carried out so far show that the function of the foot is affected by the alignment configuration of the prosthesis and by the stiffness characteristics of the plantar flexion bumper. The foot function in above-knee amputees differed from that in below-knee amputees. The results also show that the action of the foot in a typical walking cycle can be broken down into distinct phases. The events taking place during these phases can be considered in detail and related to other parameters of amputee gait. This phasic activity should facilitate the formulation of a mathematical model of the function of the uniaxial foot which is being contemplated.

Prosthetic Loading Data for the Development of Standards for Lower Limb Prostheses

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Sponsor: University of Strathclyde

Purpose — Several research programs have been undertaken at the University of Strathclyde in order to obtain prosthetic loading data during amputee activities. These data were essential in order to formulate appropriate criteria for the design and proof testing of lower limb prostheses. This work culminated in the "Philadelphia Standards" published by ISPO in 1978. These Standards, however, were based on tests performed within the confines of the laboratory, and the majority of amputees were healthy active adults who acquired amputation through

trauma. Although, since that time, data on lightweight limited activity and child amputees for level walking were obtained at the University of Strathclyde, there is a serious lack of prosthetic loading data in more realistic day-to-day encountered situations.

Progress — In the VA Rehabilitation R & D Progress Reports—1983, a portable tape recorder system capable of measuring prosthetic loading during ambulatory activities outwith the laboratory was reported. This system now has been used to acquire data from 20 below-knee and above-knee amputees of a wide range of activity levels during ambulatory activity on a variety of terrains.

It was found that the maximum axial load and anterior/posterior ankle bending moment, and the most critical loads on a prosthesis on flat surfaces were on average higher outdoors than in the laboratory by about 10 percent. Other parameters, viz. medio-lateral bending moment at the ankle and knee and anterior/posterior bending moment at the knee, were not greatly affected by the type of walking surface but rather by the alignment configuration of the prosthesis. Another significant finding of this study was that limited activity patients may at times develop loads in the prosthesis approaching those developed by active users. Statistical analysis of the large amount of data collected in order to establish the effect of various terrains on prosthetic loading is being planned. The possibility of using such data for amputee assessment also will be investigated.

Study of Alignment in Lower Limb Prostheses

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Sponsor: University of Strathclyde

Purpose — This study has shown that for any amputee there is a range of alignments that are acceptable to himself and the prosthetist. This is contrary to the widespread belief that there is only a unique configuration, the so-called "optimum alignment" which can be achieved by the prosthetist during fitting.

Progress — Twenty above-knee and below-knee amputees were dynamically aligned on a number of occasions and the range of acceptable alignments for each amputee was established. It was found that an amputee's gait is affected by the geometrical configuration of the limb (i.e., its alignment or the relative position and orientation of the various components to each other). By quantifying the kinematic and kinetic parameters of gait, it was found that it is possible for a given patient to select on the basis of biomechanical analysis the real optimum alignment from a range of acceptable alignments. From the data collected it is also possible to make recommendations on suitable bench alignment setting values. Additionally, design criteria for future alignment devices have been established.

On a long-term basis, it is planned to develop a procedure that would allow the optimum alignment configuration to be determined in the clinical situation. However, before this can be done, it is necessary to develop means for measuring alignment in the limb-fitting center. Implementation of the procedure already

developed at the University of Strathclyde for measurement of alignment was not possible as it is time consuming and requires specialist operator skills.

In order to overcome these drawbacks, a special device has been designed. It consists of a centralizing mechanism that accurately and repeatably locates the socket on a predefined axis. Two mechanisms each incorporating two bar linkages with potentiometers measure the position and orientation of the knee (for above-knee prostheses) and the foot relative to the socket axis in three dimensions. The output from the complete device is fed into a 16-channel 12-bit analogue to digital converter that acts as an interface to a microprocessor. Suitable software performs the geometrical calculations for the determination and listing of the alignment parameters, i.e., the shifts, tilts, and rotations of the various components relative to the socket axis system. A graphic display of the limb configuration also is provided as an option.

The device has been designed to be robust, relatively inexpensive, requiring minimum maintenance, and suitable for use by unskilled operators. The system presently is undergoing evaluation to determine its accuracy and repeatability.

Development of Improved Sockets for Lower Limb Amputees

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — This project has two objectives with respect to sockets: 1) to design and test sockets with flexible brims for lower limb prostheses; and 2) to design and test adjustable sockets for below-knee and above-knee prostheses for use in early fitting of amputees. Providing more comfortable sockets by the use of flexible brims is an application of results of previous theoretical work.

Progress — The adjustable sockets for use in early fitting procedures will use polypropylene sockets molded over positive models and will be constructed in such a way that the volume below the tibial condyles can be controlled easily by tightening and loosening a screw.

Prototype models of below-knee sockets with flexible brims have been fabricated and tried on test subjects. One design is essentially ready for extensive clinical trials to compare this supposedly more comfortable socket with those made using present practices.

The evaluation of results will attempt to determine how much the experimental prosthesis changes the activity level of the amputee by recording the number of heart beats and number of steps taken over an extended period. A 4-channel tape recorder worn by the amputee can record the heart beats and steps taken for a period as long as 24 hours. Heart beat and step data can be plotted against time to provide an energy consumption index and an activity level.

The sensitivity and usefulness of this technique currently is being determined. A healthy, active 37-year-old above-knee amputee has been fitted with an Otto Bock modular unit with a hydraulically controlled aritificial knee. To test usefulness, the knee is aligned in what would seem to be the optimum condition to obtain heart beat and step data under both controlled and uncontrolled conditions.

The controlled condition consists of a specified course over which the subject walks. The uncontrolled condition occurs when the subject is asked to wear the recorder for his walking hours. To test sensitivity, the same kind of data is recorded as the prosthesis is deliberately misaligned.

If this system is as sensitive and reliable as it appears to be, it should make a significant contribution to evaluation programs for all lower limb prostheses, orthoses, and methods of treatment for locomotion problems.

As soon as the sensitivity of the physiological monitoring system has been determined, the part of the study concerning sockets with flexible brims will be continued full scale. Shortly afterwards, prototypes of the adjustable below-knee sockets will be fitted to patients who are being provided prostheses for the first time.

It is probable that the two socket techniques can be combined eventually, but initial trials will be made independently.

The Effect on Gait Using Various Ankle-Foot Devices

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The development of multiaxial feet has changed the focus of biomechanic interest from the proximal to the distal aspects of the prosthesis and to the effects on ambulatory performance with the currently available array of foot-ankle devices. Even with a well-fitting socket and an appropriate suspension, the nature of the substratum will effect the ambulatory function and comfort of the patient. There is a need to evaluate the commercially available ankle-foot devices in a precise scientific fashion to establish definitive criteria for their use.

The following key questions will be addressed:

1) What bearing does stump length have on the choice of foot-ankle assemblies?

2) Do factors such as speed of walking or walking on unlevel surfaces help distinguish choices in foot-ankle assemblies?

3) What factors need to be considered in prescribing a specific foot-ankle assembly?

4) Can selected objective gait measurements be used to facilitate reaching optimum settings in alignment and adjustment of the foot-ankle assemblies?

Progress — Twenty unilateral below-knee amputees in the age range from 35 to 75 years will be tested. Stump lengths from two to eight inches will be included. Each patient will be fitted with a lined PTB prosthesis with an endoskeletal system to allow for easy change of foot-ankle assemblies. Five different foot-ankle assemblies will be tested: SACH, articulated single axis, SAFE, multiaxial Greissinger, and SEATTLE. The subjects will be given one week to become accustomed to each assembly.

The subjects will be tested with each of the five different ankle-foot devices under three conditions of walking: 1) level at three speeds; 2) ramp ascent/descent at comfortable speed; 3) lateral incline/decline at comfortable speed. They will be

instrumented with bilateral heel and toe footswitches, bilateral knee electrogoniometers, and accelerometer pack attached to the prosthesis, accelerometer assembly at the sacro-lumbar area, and a tachometer cord attached to the sacro-lumbar area.

In addition to treating the collected data for commonly used gait variables, mechanical work of locomotion will be calculated together with an efficiency figure representing the effectiveness of transfer between potential and kinetic energies. Angular accelerations of the prosthesis in both AP and ML directions will be registered. Wave forms of the knee flexion-extension, vertical and longitudinal accelerations of the body, and the tachometer will be examined for deviations. Harmonic ratios for the latter three wave forms will be calculated. Effects of perturbations induced during the stance phase will be related to the physical characteristics of the amputees in an effort to derive prescription criteria.

THE ICEPOSS System

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Sponsor: Ossur hf., Prosthetics and Orthotics

Progress — A new concept for fitting TE, TK and TA (Syme) amputees is ICEPOSS (Icelandic Pull on Suction Socket). The system consists of an injection moulded silicone socket of 10-15 centimeters and an open, ISNY type, frame with a full-ring proximal brim. The silicone socket is secured to the distal cup of the frame by screws or by a specially designed coupling device. The silicone socket fabrication is quite similar to the ICEROSS-socket fabrication. The socket is a compressive suction socket and is donned by inserting the residual limb, forcing all the air out. When donning, the amputee inserts a finger down into the socket and lets air in to break the seal. Three TK, one TE and two TA amputees are using this type of socket in Iceland.

THE ICEROSS System

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Progress — A new method for fitting below-knee and above-knee amputees is ICEROSS (Icelandic Roll on Suction Socket). The system consists of: 1) an injection moulded silicone socket that is relatively unstretchable axially but highly elastic radially; 2) a coupling device for bottom-to-bottom connection; and 3) a rigid total contact socket or alternatively a flexible socket type ISNY.

The silicone socket is fabricated over a high density plaster of paris model that is somewhat smaller in circumference than the original model. A Pelite socket dummy is made over the model and a thin rigid socket is then laminated over the dummy. The dummy is removed and silicone injected into the 2-part mould thus created. The silicone socket is fitted over the original model and a rigid or a flexible socket made over it. When donning the socket the amputee turns it inside out and rolls it over the residual limb. The coupling device is connected to a nylon tape that goes through the bottom of the rigid or flexible socket to a buckle on the

posterior socket wall. The silicone socket adheres to the skin and acts like a second skin, transferring the action of interface friction from the skin-stump sock level to the interface level between the silicone and the supporting socket. The result is a total contact suction socket with excellent suspension and load distribution properties even for very short residual limbs.

ENDOLITE—The High Technology Prosthesis

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Sponsor: Research and Development Unit, Chas. A. Blatchford & Sons, Ltd.

Purpose — International opinion over the last two decades has highlighted the need for lighter weight prostheses for patients of all categories. Clinicians have in fact specified the desirable weight limit as being 1 kilogram for the below-knee and 2 kilograms for the above-knee prosthesis. These factors were foremost in our minds when the design specifications were drafted some eight years ago for a new second generation system to replace our aging modular assembly prosthesis. The design specifications can generally be divided as follows.

Progress —

1) *The Weight Factor.* This was the single most difficult problem to solve. In order to achieve the objectives set by the clinicians; we felt a need to depart from the materials generally used in the construction of prostheses. We chose to investigate the possibilities of using high technology materials generally associated with the aerospace industry, and of these carbon fiber reinforced plastics, with a high strength to weight ratio and good rigidity seem to promise most.

Fully endoskeletal limbs with the load bearing structure packaged within a soft cosmetic foam are an ideal application for material whose relative weakness could be damaged due to impact.

In order to use a somewhat expensive material in an efficient and cost-effective manner we would need to achieve an optimized fiber/resin ratio and effective control of voids on a production basis. We chose for consideration two main structural components, the shin and the rigid keel of the foot. With assistance from the Atomic Research Establishment at Harwell, England, we were able to establish a good design and identify a production route. In order to ensure the quality and structural integrity, we had to develop and have produced sophisticated and unique special purpose machinery able to control closely the temperature and pressure cycles during the moulding process. These main structural elements within the ENDOLITE System are now in full production.

2) *Function at Knee and Ankle.* For the knee, our design department produced a compact design for a mechanism with similar functions to our established and well proven stabilized knee intended for the more active patient. A complementary pneumatic swing phase control is provided. Also available within the system is a semi-automatic knee lock usually prescribed for the enfeebled geriatric amputee. These and other alternative knee controls were designed to be fully interchangeable within the system.

At the ankle level, a new design that gives a full range of movement allowing controlled inversion and eversion in addition to plantar and dorsi flexion was produced. The resistance to motion in each direction can be varied by careful

selection and fitting of rubber elements of different hardnesses within the module. Some rotation or torque absorption and general cushioning also are provided. The MULTIFLEX ankle mechanism gives a natural action to the foot and is beneficial over rough terrain.

3) *Cosmetic Covering.* In keeping with modern systems currently available, the system has a fully endoskeletal covering that is lightweight and has a choice of outer cover, either fabric or a nylon reinforced silicone skin to give the limb a lifelike appearance.

4) *Sockets.* It was considered necessary to provide the facility for accepting sockets of any type. However, we find the most popular socket is produced from thermoplastic material, usually polypropylene. This necessitated designing equipment to drape the thermoplastic sockets over a cast of the patient's stump. Latterly, we have produced a number of ISNY sockets for ENDOLITE with soft inner sockets housed in a reinforced polypropylene outer frame.

Preliminary Results — A test program over a period of two years was undertaken in conjunction with a series of clinical trials. The Department of Health Scientific and Technical Branch at Roehampton, England, has tested and approved the system in the laboratory to standards based on the report of the meeting on Physical Test Standards in Philadelphia, PA in June 1977.

The first stage of the project is now complete with over 1000 above-knee and 1500 below-knee limbs currently in service in the United Kingdom, with a considerable number supplied throughout Europe. Our research now is directed to expand the system to other levels of amputation, notably the through hip and through knee disarticulation. Initial investigation suggests that this new technology will benefit patients with amputation at these levels.

Automated Fabrication of Lower Extremity Prosthetic Sockets

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — This project is designed to evaluate the feasibility of using computer-aided design and computer-aided manufacturing (CAD/CAM) technology to fabricate sockets for lower extremity prostheses.

The project is based on the premise that by employing a finite element computer code which uses data that characterize the shape of the non-loaded residual limb and the mechanical stiffness of the issue, it is possible to generate the shape that the socket should have in order to effectively transfer the body weight through the soft tissue and thus minimize tissue trauma and user discomfort.

Progress — During the course of the work two new pieces of instrumentation have been developed and reduced to clinical prototypes. The first system is an automated shape sensor that can characterize the surface topography of the amputee's residual limb to an accuracy of ± 0.01 inches. The second instrument is a pulsed doppler ultrasonic system that uses the sound to measure the motion of points in the tissue when it is subjected to a cyclic forcing function. The motion data are then used to calculate the elastic modulus of the tissue.

To date these instruments have been used to collect information on one above-knee amputee and a socket has been fabricated using the CAD/CAM system. The fit of the socket is currently being evaluated. If it is satisfactory, e.g., the amputee uses the socket regularly, sockets for an additional eight to ten amputees will be fabricated and evaluated.

Predictive Value of Transcutaneous PO_2 in Peripheral Vascular Disease

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Purpose — Patients requiring amputation or vascular reconstruction because of peripheral vascular insufficiency receive standard vascular evaluation and also segmental transcutaneous PO_2 measurements using an 8-channel noninvasive transcutaneous oxygen tension monitor which was developed under this project in collaboration with the Department of Electrical Engineering at the University of Washington. The preoperative results of 250 patients were correlated with the subsequent healing of the amputation and ulcers. Postoperative vascular reconstruction results of 50 patients were correlated. The relationship between peripheral sensation, clinical condition, and skin perfusion of 400 patients also were done under this study.

Progress — Data from the legs of over 400 patients with peripheral vascular disease, a third of whom have diabetes, indicate that patients with segmental $TcPO_2$ values of less than 20 mm Hg are more likely to have rest pain, ulcers, or to need an amputation within two months; furthermore, any amputation performed through an area where the $TcPO_2$ is less than 20 mm Hg is much less likely to heal. The effect of chronic limb ischemia on peripheral sensation was relatively weak when compared to the effects of diabetes and alcoholism. Cutaneous ulcers were more common in those nondiabetic patients with poor sensation, whereas ulcers in diabetic patients were unrelated to the integrity of peripheral sensation. It was found that $TcPO_2$ is a good predictor of the outcome of reconstructive surgery in patients without diabetes and is a better predictor of outcome in diabetics than is ankle blood pressure.

A Program for Evaluation of the Dysvascular Patient

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Purpose — The objectives of this program are: 1) to determine the role of lumbar sympathectomy in the management of artherosclerotic disease; 2) to obtain and analyze hemodynamic data to evaluate the potential amputee with respect to lowest level of amputation consistent with wound healing; and, 3) to evaluate the patient requiring vascular reconstructive surgery.

Progress — The research plan includes the development of instrumentation that can quantitatively and qualitatively measure subcutaneous and cutaneous blood

flow pre- and post-sympathectomy or bypass graft. Techniques being explored include plethysmography, fluorescein, and H2 clearance. Currently the development and use of these three techniques to assess the hemodynamic effects of lumbar sympathectomy are being evaluated in the research lab using the canine and primate models. All clinical cases of vascular disease are being followed by standard noninvascular procedures (i.e., Doppler, EMF, TCPO2).

The technique of H2 clearance has been used to monitor blood flow in the gastrocnemius muscle following sympathectomy in animal models. The contralateral non-sympathectomized limb was used as control. Average blood flow for the sympathectomized limb was from 33 percent to 83 percent greater than contralateral non-sympathectomized limb and the difference also was statistically significant at $p > 0.005$.

Preliminary data analysis was conducted of lumbar sympathectomy for toe gangrene long-term follow-up: retrospective review of 45 patients (50 limbs) with toe gangrene was not amenable to direct arterial surgery and was managed by lumbar sympathectomy alone. Follow-up data regarding toe salvage, limb salvage, and limb loss were compiled. At five and eight years follow-up cumulative limb salvage was 71 percent and cumulative toe salvage was 51 percent. The presence of diabetes did not significantly influence limb or toe salvage. Mortality during the immediate postoperative period was 2 percent. In the majority of patients with digital gangrene who were not amenable to arterial surgery, lumbar sympathectomy was of benefit for salvaging the limb and toes.

Using Cutaneous Photoplethysmography (CPP) in normals, there was no gradient in cutaneous pressure from the chest to the dorsum of the foot; cutaneous pressure at each level of the leg was higher than that of the chest. In patients with vascular disease, marked gradients in cutaneous pressure occurred from the chest to the dorsum of the foot. CPP was much lower in the presence of ulceration, rest pain, and/or gangrene. A cutaneous pressure of about 50 mm Hg was the predictive criterion for wound healing.

The fluorescein technique presently is being applied to the canine model pre- and post-sympathectomy.

MACH Foot Study Development

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Sponsor: VA Rehabilitation Research and Development Service

Progress — The MACH (moveable ankle cushion heel) foot project has progressed to a point where four prototypes have been made and are currently being used by amputee research subjects. These test feet exhibit 10 to 15 degrees of initial plantar flexion (before heel compression), 5 to 7 degrees of inversion, eversion, and rotation. The weight of these have run 1/8 to 1/4 of a pound less than a similar sized SACH foot.

The response from the amputees has been overwhelmingly in favor of the foot. While we are very satisfied with the function of the present design, there are problems with the fabrication procedure. Some changes in the design of the ankle joint need to be incorporated with a new method of fabrication that will be less labor intensive than the current procedure.

SACH Foot Study

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Purpose — The SACH foot (solid ankle cushion heel) is frequently prescribed for below-knee and above-knee prostheses. The objective of this portion of the study was to evaluate the static and dynamic characteristics of the SACH heel. Static measurements of the SACH heel have been performed.

Progress — This study has demonstrated that there is little difference between the static characteristics of soft, medium and regular heels on the SACH foot. The dynamic response of the SACH foot has been investigated in two amputees using data obtained on two below-knee amputees from the gait analysis laboratory in San Diego at Children's Hospital. These data have been analyzed and have been used to help analyze a dynamic model of the SACH heel.

B. Lower Limb

2. Below-Knee

Computer-Aided Analysis of Below-Knee Socket Pressure

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Progress — There were two areas of concentration during the first year of this project: 1) computer modeling of the socket and limb; and 2) development of a system for measuring socket-limb interface pressures. The major achievement in the first area was the construction of the initial finite element model. Extensive software revision was necessary to accomplish this task. The finite element programs were converted to run on a new CYBER 180/845 computer and enhanced to accommodate the features of the model. As a first order approximation, the model of the prosthesis and limb assumed linear material properties, homogeneous soft tissue properties, a rigid socket, and small strains and displacements. The geometry of the model was derived from a plaster cast of a subject's limb and CT scans.

For the initial model studies, an approximate value of tissue stiffness was used, but in the future, soft tissue stiffness will be determined experimentally for each subject. An instrument that simultaneously measures force and displacement when gently pressed against the skin has been designed for this purpose. A series of computer runs were made to examine the effects of the socket liner and soft tissue stiffnesses on the stresses (pressures) calculated for the model. Preliminary results have been encouraging; the pressures at the socket-limb interface of the model were in the same range as those measured experimentally by previous investigators.

Work on the interface pressure measurement system focused on the development of a suitable pressure transducer. A commercially available diaphragm pressure transducer was modified. In the current design pressure is transmitted through a column of water to the silicon diaphragm. Several different fluids and fabrication methods were attempted before a stable device was produced. Special fixtures were designed for mounting the transducers on the socket, and a platform was built to facilitate loading the transducers during calibration. An LSI 11/23-based data acquisition system is being set up to monitor seven voltage inputs simultaneously. Using the calibration data for each transducer, the computer will calculate the pressure at each measurement site on the socket. The software for data collection and processing has been written and tested.

Comprehensive Alignment Procedure of Below-Knee Artificial Leg

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Sponsor: Israel Ministry of Defence

Purpose — Three major factors are involved in the successful delivery of a leg prosthesis: adequacy of the stump-prosthesis interface, properties of the main components, and mechanisms and alignment of the prosthesis. In this study we investigate all three factors and develop procedures for objective optimization of prosthetic fitting. We believe that it will be possible to clinically apply these procedures in the actual process of individual fitting of prostheses.

Progress — For both the socket geometry and the alignment studies, gait analysis is used for evaluation of performance. Gait is monitored on a 10 m walkway, including at halfway two Kistler piezoelectric force platforms, from which the foot-ground forces are recorded. A complete television system consisting of three TV cameras connected to a special effect generator and video tape recorder is used during the experiments for kinematics measurements and synchronization of this measured kinematics with the actual forces.

To study the effect of variation of socket geometry via the PT insertion, the sockets of the prostheses of the subjects who take part in the procedure are modified to enable variations in the geometry of the PT insertion and attachment of load cell.

The results are obtained, both numerically and graphically, in terms of the geometrical parameters of a torus for the condyles of the endoprostheses. These include values for both the shape and location of the torus. Geometry of the tibial component represents the tangents of the femoral surface in subsequent positions of motion. The optimal positioning of the endoprosthesis, for which the gliding index becomes minimal, is obtained at the margins of the anatomical constraints. It corresponds to the innermost possible location into the femur. Apart from determining the obtained new surfaces, the present model allows us to evaluate existing endoprostheses from the point of view of their gliding motion and to relate this to their clinical performance.

Study of adaptation and of compensatory mechanisms of amputees walking with prostheses is made on patients using modular prostheses. These are advantageous because the prosthesis alignment can be altered easily and the

resulting gait performance evaluated. The same applies to the deliberate introduction of variations of the prosthesis components. Optimization of alignment is studied through an elaborate monitoring technique enabling a systematic alignment of the prosthesis for the achievement of the best possible performance.

Preliminary Results — The results show a strong dependence between positioning of the PT insertion and the force transmitted there. Correct positioning of the PT insertion is established for each individual subject when gait performance is optimal. The parameters, for which optimization is performed, are selected for each patient from both subjective and objective information.

With respect to adaptation, our results clearly indicate that in amputees a symmetry function seems to be automatically reached in extremely different alignment conditions. Symmetry values are different from patient to patient, probably depending on the degree of severity of pathology and on the ability of the patient to generate compensatory mechanisms. Other functions, however, mainly those related to the detailed activity of the prosthesis as compared to the sound leg, clearly reflect the alignment variations introduced. Apart from parameters such as impulse ratio, these functions include minimization of observed disturbances which tend to appear on the force curves in position of incorrect alignment. This analysis, conveniently done on the computer, is characterized by determination of the time duration of the different phases of the disturbance on the anterior-posterior (AP) force.

Presently, the developed techniques are being refined to enable easy and convenient application for clinical procedures of prosthetic fitting, including socket geometry, dynamic alignment and component selections.

Lightweight Three Component Below-Knee Prosthesis

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The objective of this study is the development and testing of a new design for below-knee prostheses that will combine the advantages of a lightweight design, prefabrication of shank and foot components, a more foolproof method of alignment, and improved foot function and gait performance.

Progress — The development state of this project is presently 75 percent complete. Nine of the 12 initial mastermolds for the shank portion of the prosthesis have been completed. Two others are in various stages of completion.

During this time, numerous test shanks have been laminated from the completed mastermolds. A laminate, consisting of polyester resin with fiberglass and carbon fiber reinforcing, is being used. The resultant weight of these shanks vary from 11 to 13 ounces, depending on the shank size.

Master positive models of the foot component have been completed for ten of the initial 12 feet. Eight of these have been converted into master molds. Three polyurethane foams of varying free foam density have been obtained and are currently being evaluated for patient use.

Patient testing and evaluation have begun for the Three-Component Prosthesis. Four amputee research subjects have been fitted with prototype prostheses. The weights of these finished prostheses are 1.75, 2.15, 2.25, 2.5 pounds (without shoe). Patient acceptance has been very high in terms of function, comfort, cosmesis, and weight. The prosthesis also has proven to be durable with no structural failures in up to two-and-a-half years of prosthesis use.

Optimum Prosthetic Foot Characteristics for Dysvascular Below-Knee Amputees

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Sponsor: VA Rehabilitation Research and Development Service and Rancho Los Amigos

Purpose — The purpose of this study is to reduce skin breakdown in dysvascular patients, decrease compromise of cardiac, respiratory, and musculoskeletal systems by improving energy expenditure and reducing unwanted pressure over the anterior tibia inside below-knee prostheses.

Progress — Below-knee amputee gait can be optimized by adjusting the heel firmness and keel length of the SACH or SAFE prosthetic foot. This project is studying the effect of varying prosthetic foot heel compressibility and prosthetic foot keel length on velocity, stride length, single support time, cadence, heel dwell time, EMG, joint torques and dynamic heel compression.

Volume Changes Occurring in Postoperative Below-Knee Stumps

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Purpose — A frequent problem occurring during the rehabilitation of postoperative amputees is how to determine precisely when the stump is ready to be fitted with the first permanent prosthesis. Inaccurate estimates often lead to ordering a prosthesis at a time when the stump volume is still changing. This results in stump-socket disparities, often the cause of pain and skin breakdown, necessitating a new prosthesis.

Progress — A study was completed that focused on stump maturation procedures, monitoring stump dimensions, determining when to fit the first permanent prosthesis, and the efficacy of the choices. Three stump volume reduction methods included: 1) elastic wrap, 2) plaster cast and pylon; and 3) lined plastic laminate socket and pylon.

A water displacement method was used to monitor stump volume. Stump circumferences were measured with a tension-tape at two and four inches from the distal aspect. Among patients demonstrating a definable decline in stump volume as a function of time, the first permanent prosthesis was fitted when the rate of change in volume reached 1.0 ml/day. Among those not showing a definable decline in stump volume, the prosthesis was fitted after 70 days on the program. Patients having been fitted with their prosthesis were followed for the duration of the project by collecting volume and circumference data bimonthly.

Preliminary Results — Nearly 80 patients were enrolled in the project. Over half of them discontinued for a variety of reasons including stump healing problems, further surgery, disinterest, moving away, and death. The final data treatment included 36 patients who were approximately equally distributed among the three methods of stump volume reduction. Approximately half of the sample demonstrated a definable decline in stump volume as a function of time. The other half did not; most of these, in retrospect, were presented with a compromised cardiovascular system indicating a tendency to venous pooling.

The lined laminate plastic socket and pylon showed the fastest decrease in volume and the elastic wrap showed the slowest. Two reasons for the results with the elastic wrap: 1) all patients were not candidates for the plaster cast or the plastic laminate socket for health reasons; and 2) patients did not ambulate weight bearing on the amputated side prior to being issued the first permanent prosthesis.

A high correlation existed between circumference measurements and stump volumes. In most cases, the correlation was significant to the $p = 0.01$ level.

Effects of health status resulted in an inability to satisfactorily characterize a stabilization point either by volume or circumference change. However, of the ten patients followed for the longer time, the results suggested potential cost savings and greater comfort to the patient. The performance included one for over three years, four for over two years, two for over one year, and three just short of one year. Three others were discontinued before end of the project: one requiring amputation on the contralateral side, and two for looseness of fit at about nine months each. The latter two were in the category not showing a definable decline in stump volume prior to being fitted with their first permanent prostheses.

Development of the ISNY Flexible Socket System for Below-Knee Amputees

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — In approaching the problem of the ISNY Flexible Socket for the below-knee amputee, the following design specifications were formulated:

1) that the frame capture all of the desired weight supporting areas of the stump, *viz.* patellar tendon, medial tibial flare, tibial and fibular shafts, popliteal bulge and distal end; cover no more than 40 to 45 percent of the stump surface; and, be as lightweight as possible;

2) that the socket insert be of low density polyethylene and of approximately the same flexibility (approximately .055 throughout) as that utilized in the above knee design; and

3) that the wearer of the socket require only a nylon sheath or at most a one-ply cotton sock.

Progress — Two designs were developed to meet these criteria: one involving a helical frame and a second more rigid structure utilizing vertical struts.

After a substantial number of exploratory fittings, six ISNY below-knee prostheses have been delivered for full time wear — two of the spiral and four of the three strut design. Four of the above have been worn over a two-month period and the last two over a two-week period. All six wearers consistently report that

both ISNY designs are superior to conventional sockets by virtue of providing more intimate fit, being lighter, cooler, having better suspension, and necessitating fewer stump socks, thereby enhancing comfort and reducing the chances of integumentary lesions.

A number of additional patients are now in the process of being fitted with the two ISNY designs as well as conventional PTB sockets. Each socket is being fabricated over a single modified cast for wear in our laboratory to permit comparative reactions to all three devices under controlled conditions.

Analysis of Below-Knee Suspension Systems: Effect on Gait

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — It is well known that the main purpose of a given suspension for a below-knee prosthesis is limb retention, but the specific effects on other areas of stump-socket biomechanics are not as obvious. Factors such as restrictions of knee range of motion either by suprapatellar-supracondylar socket enclosure not only imposes specific effects on life style but also on gait patterns and on locomotory work expenditure. In addition, certain suspension modifications designed to minimize axial stump-socket movement may alter the basic biomechanical principles of the prescribed prosthetic device. What emerges from clinical observations is the need for guidelines and specific prescription criteria for specific suspension systems.

The key questions expected to be answered through this study are:

1) What are the specific prescription criteria for a suspension system for a given patient?

2) How does patient activity level effect the choice of suspension system?

3) How do stump characteristics and physical capability effect the choice of suspension system?

4) What gait variables, measured or derived, are useful to differentiate effects on gait resulting from different suspension systems?

5) What gait variables, or combinations of variables, serve to discriminate relative effectiveness of a given suspension system?

6) What are the advantages and disadvantages of a given suspension system?

Progress — Twenty unilateral below-knee amputees in the age range of 40 to 65 years are tested. Each is tested with the following seven suspension systems: 1) supracondylar suprapatellar; 2) supracondylar; 3) PTB cuff; 4) PTB cuff with waist belt; 5) PTB cuff with figure-of-eight suprapatellar strap; 6) rubber sleeve; and 7) articulated supracondylar wedge. The plan employs one PTB-type prosthesis, altered successively in the order listed. Each subject is expected to wear the test prosthesis at least two hours per day between weekly test appointments.

The subjects are instrumented with bilateral heel and toe switches, bilateral knee electrogoniometers, an axial stump-socket movement detector, a gimbal mounted triaxial accelerometer mounted at the sacrolumbar area, and a cord connected to a stationary tachometer. The subjects are instructed to walk at three

different speeds: 1) comfortable; 2) faster than comfortable; and 3) slower than comfortable. The purpose of the fast and slow speeds is to provide challenges to the systems.

In addition to treating the collected data to the commonly used gait variables, mechanical work of locomotion is calculated together with an efficiency figure representing the effectiveness of transfer between potential and kinetic energies. The axial movement of the stump in the socket is analyzed for amplitude and for when in the gait cycle the signal occurs. Wave forms of the accelerometer and tachometer are treated for harmonic ratios. Deviations in the knee, accelerometer, and tachometer wave forms are identified and correlated to the suspensions. This scheme of testing allows comparative biomechanical analyses within each subject and a basis for comparison among subjects to ascertain the effect on gait by the seven different suspension systems.

Preliminary Results — Ten amputee subjects have been tested to date. Classification methods operating on the biomechanic variables demonstrate distinction among subjects and discriminate among the suspensions. It is too early to attempt to determine why the subjects distribute as they do.

Ten normal adult subjects were tested at various combinations of stride length and stride frequency. The results were analyzed and deployed into the evaluation of amputee gait.

Future Plans — We plan to continue the test and data processing protocols and to determine the relation between physical characteristics of the amputee subjects and the manner in which they distribute in locomotor performance.

Biomechanical Evaluation of ISNY Flexible Socket

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Sponsor: Osaka Rosai Hospital

Progress — Using linear motion transducers and strain-gauge pressure sensors, we are evaluating the ISNY flexible sockets to determine shape and inner pressure during walking. We find that the degree of socket movement is not remarkable and change in socket shape seems not to correspond to bulging of each muscle but mainly to the pressure of the stump acting as lever arm.

The comparisons of inner pressure between the ISNY sockets and conventional hard sockets indicate that the inner pressure is almost the same. At the present stage, we believe that, biomechanically, the ISNY socket is nearest to a suction socket with a soft liner.

We also are measuring thickness of the ISNY sockets on numerous spots.

B. Lower Limb

3. Above-Knee

[See also pg. 210]

Survey of Prosthetic Knee Joint Design Criteria

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Progress — The survey included a review of present-day knee mechanisms and research developments in knee design and control. No device has yet fulfilled all known requirements of an artifical knee mechanism although many have solved some of the problems.

A questionnaire survey of 50 amputees was carried out in interview form. Questions were concerned with the amputees' opinions about their present limbs, walking ability, knee joint problems and with suggestions for improvements to limbs as a whole and to knee joints in particular. It was found that 85 percent of the respondents would like a power-assisted limb to facilitate in activities such as stair climbing. However, only 36 percent of the patients would be willing to carry an external device.

A biomechanical evaluation of three conventional knee mechanisms (free, locked, and safety types) was performed in which four amputees of various activity levels were analyzed for uphill, downhill, and level walking. Forces and moments at the lower limb joints, distance-temporal parameters, and hip and knee angle data were collected for each situation. The function achieved from each knee depended on the ability of the amputee to control the limb. Interestingly, from a biomechanical point of view, it was found that in three out of the four patients tested, performance was better with a knee other than the one originally prescribed to them. An element of patient dependency regarding the achieved function of different knees indicates the need for a system of prosthetic prescription to cope with individual requirements.

Microcomputer-Controlled, Individualized, Multimode Prostheses for Lower Extremity Amputees

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Purpose — This research aims toward improving the above-knee amputee's mobility through development of new computer-controlled knee mechanisms and new algorithms for their control.

Progress — The most fundamental assumption in the program is that a prosthesis should have characteristics which are custom tailored to the user and to the user's current mobility task, (i.e., multimode; changing according to the disabled person's need such as flat walking or stair climbing). This type of variable or versatile behavior is being sought through microcomputer control of new knee

mechanisms. The most conservative version of such a prosthesis uses a knee mechanism that can only absorb energy. The most advanced concepts include knee mechanisms that contain motors and can also operate as generators and energy storage elements. Such energy regenerative artificial legs will allow more symmetric gait by providing active stance-phase control. Such a mechanism would not, however, provide the large power and energy needed for tasks such as climbing a long staircase.

The project tasks include:

1) Developing and evaluating control algorithms for both stance and swing phase;

2) Developing new knee mechanisms that allow control by computers;

3) Developing control algorithms which optimize energy regenerative systems; and

4) Assessing the marginal value of active mechanisms for providing gait symmetry and stability.

The ultimate objective is the improvement of the above-knee amputee's mobility and the furthering of his/her independence by meeting specific needs.

Sensory Feedback System for Above-Knee Prosthesis

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Sponsor: Osaka Rosai Hospital

Purpose — Our goal is to develop a sensory feedback system for the above-knee prosthesis which is useful in daily activities.

Progress — We have constructed a system in which auditory feedback of knee angle is transmitted to the amputee. Presently, we are testing this system with normal persons fitted with simulated prosthesis. We do not find any effective results of sensory feedback in the prosthetic training. However, we are planning to evaluate our system in many situations, e.g., walking on un-even ground, a slope, or a zigzag course.

Evaluation of Load-Actuated-Brake Knee for Above-Knee Prosthesis

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Progress — Using pylon study, knee moment was measured on the above-knee prostheses equipped with load-actuated-brake knee during walking. We found that load-actuated-brake knee can not play any role at the moment of heel contact. It can prevent knee collapse after weight is borne but at the same time interference of knee flexion at the end of the stance phase resulted.

Therefore, we conclude that the load-actuated-brake knee is not appropriate for active or inactive above-knee amputees. We are presently recording EMG on these amputees.

Myoelectrically Controlled Above-Knee Prosthesis

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Progress — Two configurations were developed. The first system (a) employs four hydraulic valves, one liquid-air reservoir, one actuator piston and one liquid sump. The second system (b) consists of an additional pneumatic valve and a split liquid-air reservoir.

a. *Single Reservoir System.* For this system, the energy is stored in a single liquid-air reservoir. The control is achieved by opening groups of valves and keeping the others closed. There are six distinct combinations, yielding six linear models. The control mechanism chooses one of these configurations. The choice is based on the pressure in the liquid-air reservoir, A and B sides of the piston, along with the direction of the desired actuator force and piston velocity. The mathematical model was developed and the simulation results were obtained. These results reveal that the system does not conserve enough of the available energy.

b. *Split Reservoir System.* The single reservoir system model was modified to overcome the energy conservation problem. A considerable amount of energy can be retrieved by splitting the liquid-air reservoir into two compartments. In many circumstances it is possible to discharge one part of the reservoir while charging the other. Therefore, the energy which was lost by discharging to the sump in the case above is now conserved in the system. Furthermore, a pneumatic valve between the two compartments of the reservoir adds an extra dimension to the control. Systems now can be switched among 14 linear models versus six in the single reservoir case. The simulation results for the split reservoir system demonstrated a substantial and acceptable improvement in the performance of the force actuator.

The next phase of the modelling and simulation will study cascading the split reservoir system. The cascade will further separate the reservoir system into high and low pressure compartments.

In the projects' *Time Series Studies* spectral changes in the surface EMG have been characterized by autoregressive (AR) models and used to detect the direction of limb movement. Such time series models prewhiten the EMG signal generated during the activity for which they are matched. Assuming that the signal fits one of the time-series models preconstructed for each limb function, the probability of occurrence of each motion has been computed from the residual sequences from each filter and a multiple hypothesis test has been successfully implemented to select the most likely limb function. The prewhitened EMG sequence also is being used to estimate the magnitude as well as detect the direction of limb motion.

Multichannel myoprocessors are being investigated in order to increase the reliability of limb function classification and the fidelity of muscle force estimation by incorporating the spatially-distributed information contained in the surface EMG. In preliminary studies, multichannel processors have been shown to be less sensitive to the spatial shifts in myoelectric activity observed during different limb function. Initial testing also indicates that multichannel controllers operate more reliably over a wider range of input conditions than processors relying on more limited spatial information.

Recent progress has been made in estimating muscle force as well as limb function from a time-series system. Time-series processors have, in the past, yielded only binary decisions. This research is unique in its attempt to develop a signal from a time-series system which is proportional to force and simultaneously specify magnitude and direction of movement. The work in progress has attempted to estimate muscle force from multiple channels of serially dependent EMG data by first prewhitening the EMG with the AR filters used for function classification, obtaining a polled estimate of prewhitened signal variance, and fitting a power law relationship to the variance signal and force. Testing and evaluation of the complete myoprocessor is underway.

Software has been developed and experimental data collected to examine the effects of contraction level, electrode position and number, and AR model building on the performance of both the limb function classifier and force estimator.

The project also has included *EMG Pattern Studies*. Data qualification procedures have been applied to raw, processed, and patterns of processed EMG. In addition, linear discriminant function (LDF) coefficients from static spatial pattern recognition limb function classifiers, and estimated and actual joint moments also were analyzed. Static refers to classifiers that are obtained from a single initial training and are not modified as time goes on. A repeatable task of tracking a trapezoidal waveform with medial-lateral axis knee moment has been designed to allow examination of data from isometric-isotonic and isometric-anisotonic (linearly increasing force) muscle states. Stationarity of both the means and variances of the aforementioned variables was examined on the second, minute, and hour scales.

The ability of the static spatial pattern recognition system to recognize the intended limb function of the amputee in terms of force magnitude and direction has indicated adequacy of the fundamental model structure. Current studies in adaptive spatial pattern recognition methods have been aimed at transforming the minute and hour scale nonstationarity of the estimated joint moment mean to a stationary space, such as the observed joint moment mean.

Geriatric Prosthetics: Design and Development of an Improved Above-Knee Socket

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Purpose — The overall objective is to develop an improved above-knee prosthesis for geriatric amputees. The primary concentration presently is on the stump socket interface where an increase in comfort is sought. The plan is to apply force in such a way as to obtain uniform pressure that would be expected to provide the most comfort.

Specific objectives are to examine the external elements of residual limbs as well as internal anatomical and physical characteristics, and to develop cross-sectional socket patterns for geriatric amputees. The subject population is planned to allow comparison of geriatrics versus non-geriatrics, amputees versus non-amputees, and males versus females. When sufficient data are collected, a socket

configuration will be designed and fabricated and geriatric amputees will be fit with it for evaluation.

Progress — The physical and physiological parameters that form the database for the related study of the residual limbs have been organized into a form adaptable for computer use to allow storage and future comparisons. The necessary equipment for performing the involved measurements has been obtained and the data collection system has been tried on several patients.

Various systems for measuring tissue compressibility have been tested. For example, brims for the perineal area have been made of thermoplastic to contain the area under study while tissue compressibility was measured with a force gauge adapted to give additional readout concerning the depth of displacement. Trials have been performed with the stump relaxed and with isometric contraction. Alternative systems, including an airtight drum made of ortholen and latex applied to the stump's brim area to allow pneumatic force to be applied equally throughout the area under consideration, are being evaluated.

Data from tissue compressibility studies will be reduced to cross-sectional diagrams that can be compared. These diagrams will contribute to the design of an alternative socket configuration for geriatric amputees.

C. Upper Limb

1. General

Quantification of the Functional Capability of Upper Extremity Amputees

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Purpose — This project will develop a technique for quantification and measurement of the upper extremity functional capability of able-bodied and disabled persons. The technique being developed has a sound theoretical basis: dynamic optimization theory is used to produce a single meaningful number derived from accessible measurements (such as myoelectric activity, speed, range of motion, etc.) and provide an essential link between measured performance and inferred functional capability. It also has a sound practical basis: performance will be measured on specific tasks that represent the functional role an upper extremity prosthesis can realistically be expected to play.

Progress — In previous work, dynamic optimization theory successfully predicted patterns of muscle activation of an able-bodied person maintaining one posture of the forearm against changing gravitational loads. More recently, the approach has been used to describe all of the major kinematic features of voluntary upper extremity pointing motions of an able-bodied person. This work demonstrates the

feasibility of the approach. In this project, the mathematical technique has been refined to separate the analysis into two separate components, one dealing with the static constraints of the non-linear geometry of the musculoskeletal system, the other accounting for the dynamics of posture. The benefit of this separation is that realistic representations of the moving limb can be dealt with more simply. The analysis has been extended to provide a description of the maintenance of any posture of the forearm against changing loads.

A unique approach to the assessment of the causes underlying the functional disability of an amputee using a prosthesis is under development. The disability of an amputee using a prosthesis can be attributed to many causes: sensory loss, damage to the amputee's nervous system, poor mechanical performance of the prosthesis, poor interfacing between amputee and prosthesis. In this project, we will attempt to determine how much of the observed functional deficiency can be attributed to the dynamic performance of the prosthesis itself. To do this we have developed an arm brace (similar to an orthosis) that allows us to add passive dynamic loading to the arm of an able-bodied subject. With this device we can mimic in the able-bodied subject the relation between muscular activity and arm motion an amputee, using a myoelectrically-controlled prosthesis, has to deal with. For example, the maximum speed of elbow motion can be restricted to that of the prosthesis. Our immediate plans for this device are to use it to measure how much of an amputee's dysfunction can be duplicated in an able-bodied subject (with no sensory loss, neural damage, etc.) simply by limiting the dynamic capabilities of the limb.

One important requirement for our experimental work is a clean, high-fidelity measurement of myoelectric activity. A new, improved method of processing myoelectric activity has been developed. The processing technique is based on a mathematical model of surface myoelectric activity, from which the optimal estimator of muscle force was derived. This optimal processor has now been implemented using microprocessor technology and yields about an order of magnitude improvement over conventional processing techniques. A major advantage of digital microprocessor implementation is that the tedious but essential calibration process is performed automatically without user intervention. This is an important step towards making this new technology accessible on a turn-key basis to a clinical user with no specialized knowledge of computer programming.

Feasibility for Innovation and Improvement of Body-Powered Upper Limb Prostheses

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Purpose — Standard body-powered upper limb prostheses have not changed significantly since developments in the 1950's spurred by World War II. They still employ aircraft technology using shoulder harnesses and steel cables for operation.

Estimates place the number of arm amputees in the U.S. at 100,000 with 50 percent actually wearing prostheses. Estimates further suggest there are 45,000

body-powered and 5,000 externally-powered arm prostheses in use. However, there is little research being conducted to improve body-powered systems.

The objective of this project is to assess the feasibility of effecting innovation in body-powered arm prostheses toward the ultimate goal of increasing their acceptance and use. The need is well documented.

Progress — The first step was to conduct a survey of amputees and professionals to assess what wearers like most and like least about their prostheses and to solicit ideas for change. (The results of the survey are described in the Winter 1985 issue of *Clinical Prosthetics and Orthotics*.) Fundamentally, arm amputees strongly desire improvement and rate: (1) function; (2) comfort; and (3) appearance of most importance to them. In analyzing the results of the above survey, the force transmission system is critical to effecting improvements in the function, comfort, and appearance of arm prostheses.

The second step was to evaluate ways to increase the efficiency of the force transmission system. Various combinations of plastic and steel cables and housings were tested along with a prototype hydraulic control system. (Results were presented at the 1985 annual conference of the Rehabilitation Engineering Society of North America.) The hydraulic system has good potential for increasing the efficiency and for allowing significant improvements in body-powered upper limb prostheses.

Future Plans — The next step will be to further pursue the use of hydraulics for transmission of body forces from the amputee to the prosthesis. The plan is to develop a clinical prototype system and evaluate it in use with arm amputees.

Myoelectric Prosthetic System

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Sponsor: National Institute of Handicapped Research

Purpose — The purpose of this project is to develop modular electronic components for the control of electric-powered prostheses. The components consist of:

- *NU 126 Myo-Trode* — An active encapsulated electrode to be used with one of several different processors for controlling electric-powered terminal devices.
- *NU 110 Myo-Processor* — A single-site signal processor with a single output for controlling a powered hook such as the Michigan Child's Hook or the Hosmer/Dorrance Prehension Actuator.
- *NU 112 Myo-Processor* — A two-site signal processor to control a motor in two directions for use with the NU Synergetic Hook or any commercially available electric hand, hook, or elbow.
- *NU 114 Myo-Processor* — A single-site signal processor to control any hand, hook, or elbow in two directions.

Progress — All systems are designed with low power CMOS devices which permit the use of small batteries. Construction utilizes Surface Mounted Device

(SMD) techniques for extremely small, reliable circuit packaging.

A manufacturer working with the Northwestern University Rehabilitation Engineering Program has completed a prototype production run of the NU 126 Myo-Trode and the NU 110 & 112 Myo-Processors. Field evaluation utilizing the electronics is being conducted by the manufacturer.

Our laboratory has completed five fittings for evaluation: two below-elbow prostheses using interchangeable hand/hook, one above-elbow prosthesis using a myo-electric hand and manual elbow, one shoulder disarticulation prosthesis using the NU 114 single-site processor for hand control and one partial hand prosthesis. The partial hand was fitted on a five-year-old child. The miniature size and low power requirements of the system facilitated fabricating a slim, cosmetically pleasing prosthesis for a small child with a partial hand amputation.

Multifunctional Compliance Hand Prosthesis — The LSU Spider Hand

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Purpose — The control aspects of hand prostheses have substantially improved in the last two decades. However, many patients find the mechanical structures and the associated functional performance still unacceptable. In particular, the following factors presented disadvantages and need additional attention:

- weight
- rigidity of graps
- limitation of three jaw chuck or rigid digits grasp (i.e., inability to consistently grasp irregular objects with equal pressure at all five fingers)
- cost
- reliability
- sensory feedback from all fingers.

The hydraulic approach was selected as the actuator design concept and lightweight plastic as the structural and packaging material.

Progress — A prototype hydraulic activator unit was developed and is currently being tested. The prototype includes a pressure distribution chamber to which six cylinders are attached. The actuation cylinder develops pressure in the unit by means of its piston deflection, which could be accomplished by a lever attached to a Bowden cable or by an electric motor controlled with myoelectric signals. On increase in pressure in the chamber, each deflection of cylinder fluid produces movement in its piston that is coupled kinematically to the finger, inducing the grasping action. As a finger encounters resistance on contact with the object to be grasped, the contact pressure remains constant until all fingers touch the object, while the first-to-touch finger does not move or apply an additional pressure. Pressure is distributed evenly to all fingers, inducing equal pressure grasp. The hydraulic medium in the chamber is a "solid silicon" fluid that eliminates the risk of spillage. For sensory feedback purposes the equal pressure grasp principle requires only a single pressure transducer that may be incorporated in the distribution chamber, eliminating the need for multisensors in each finger.

Utilization of a viscoelastic medium allows a certain amount of compliance during the grasping cycle, thus simulating to some extent a human grasp with its soft-tissue deformation.

Current work focuses on testing the activator prototype and developing an electrotactile-based sensory feedback system.

Considerations for New Design of Human Hand Prosthesis

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Purpose — The MTM-1 system is employed for the development of 'performance profiles' for impaired individuals. The study deals with hand amputees who are involved in manual tasks and is aimed towards improving their occupational potential. The informed procedure of performance profiles is based on micro-motion analysis which uses MTM-1 for definition of motion patterns and on biomechanical consideration for the locomotion of the amputated organ. The procedure is useful as an objective evaluation of the amputee's performance and is directed to the assessment of his occupational abilities in the non-sheltered situation.

The informed performance profiles serve as criteria for mechanical design of manipulative aids for amputees to replace their lost hand. In this study, an improvement of the standard hook that advances the manipulative abilities of the amputee is suggested.

Progress —

The Performance Profiles. Characteristics and limitation of repeatable motion elements of amputees who wear a standard 'lyre-shaped' hook was investigated by using the MTM-1 procedure for manual operations in terms of their motion elements. The five motion elements involved in this investigation were reach, grasp, move, position, and release. A task layout was established for the investigation using two task boards, 12 objects, and a standardized routine of task handling. The 12 objects differ in shape (ball, cylinder, cube and triangle), weight, and size (small, medium and large). The objects were picked up from their stations on one task board, transferred and positioned in appropriate recesses on the other task board.

Analysis of Prosthetic Design. The performance profiles obtained from micro-motion analysis of the deviation in performance between amputee and non-amputee individuals defined the motion element "grasp" to be the main cause of manual time delays for all the four basic geometrical shapes. Two improved versions of the tested hook were developed in the Work Study Laboratory at the Industrial Engineering Department of Technion-Israel Institute of Technology. The new configurations of hooks were based on the Dorrance Lyre-shaped hook fingers and are easily fitted to any regular prosthesis. The improvements were designed according to the criteria defined in the micro-motion study and ADL (activity of daily living) considerations from objective evaluation of amputees movements. Both versions have lyre-shaped hook fingers with smooth outer

surfaces to allow easy access for entering pockets and sleeves. The hook fingers have rubber bonded to their inner sides to provide the necessary friction for holding smooth objects and for preventing possible vibrations if they occur. One of the versions has two fixed thumb fingers originating at the base of the main fingers which forms a double forceps finger device for the better maintenance of grasp ability of multiform and rounded shapes. These supporting fingers were designed curved and of appropriate size in order to embrace large spherical shapes. The added fingers have additional embossments which have a swivel ability to provide a tight grip potential for carrying handles attached to weight (attache cases, bags, etc.). A third version was designed with two additional fingers with swivel ability on ratchet type hinges. These provide a widely adaptable supportive ability to the basic lyre-shaped fingers. When closed, the two double fingers form a nearly closed curve which enables the clasp of objects with parallel surfaces and enables the support of rounded figures. Such designs of hook fingers may reduce the tendency of objects to eject as prehension forces are increased as well as making a better supportive contact when gripping objects with parallel surfaces and spherical contour lines.

Design Evaluation. Evaluation of the improved versions in relation to the standard Dorrance hook followed. The evaluation was based on a micro-motion comparison of motion element grasp for performance ability of the three hooks. The same task was performed by a small sample of individuals who performed the task three times, each time with another hook. The versions developed in this study provided an improvement in hook performance ability with small and large objects. For the triangle, cylinder, and ball, which are more problematic shapes, there was also relevant improvement.

Cosmetic Covers for Upper Extremity Prostheses (Male/Female)

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Purpose — A goal of this program, started in April 1985, is to develop realistic and durable cosmetic covers for hand and arm prostheses for men and women. A basic thesis is that the subject's remaining hand is to be used as the master for fabricating the prosthetic cover (as opposed to using a stock glove). Advanced materials and techniques are to be applied in this program. These include: silicone rubber primary molds, use of a 3-D reversing pantograph, cast thin shells for texture transfer, castable polyurethane final molds, quantitative approaches to intrinsic coloration, and durable silicone rubber materials for the covers.

Steps in the projected overall procedure include: 1) making a precision mold of the hand and arm; 2) making a rigid cast from the primary mold; 3) using this cast as the master from which to make a mirror image with the reversing pantograph; 4) providing accurate skin texture to the mirror-image form by applying thin wax overlays cast from the silicone rubber primary mold and bridging and texturizing the gaps between these; 5) making a final mold (e.g., evertable or split polyurethane elastomer) from the mirror-image master; and 6) fabricating the prosthetic cover in layers, using intrinsic coloration for heterogeneities and mass tones.

Progress — Included in the efforts this year have been: 1) studies of materials for molding procedures and for fabrication of the covers; 2) investigation of methods for making a precision primary mold (one-piece evertable with split mother mold, two-piece using custom-molded alginate resting base to define the split line, and two-piece cast as one-piece with specially embedded alignment keys); and, 3) fabrication of the reversing pantograph.

Future Plans — Further work will include development studies on fabricating and texturizing the mirror-image form, on making the final mold, and on fabricating the prosthetic cover itself. Wearer studies and technology transfer to prosthetists also are planned.

Orthoses and Prostheses for Partial Hand Amputation/Evaluation of the Hosmer Contour Terminal Device

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Sponsor: Department of Veterans' Affairs

Progress —

Orthoses and Prostheses for Partial Hand Amputation. Simple devices are made of light plastics in order to allow amputees bimanual activities.

Evaluation of the Hosmer Contour Terminal Device. Evaluation was performed on a series of ten patients with below- and above-elbow amputations. The Contour hook needs a cable approximately four centimeters longer than the classical hook. The activation lever arm is shorter so that more power is needed to open it for the same number of elastic bands.

Design of Prehension Systems for Upper Limb Amputees

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Sponsor: VA Rehabilitation Research and Development Service

Progress — Our research work has centered on the refinement of the synergetic power base for the prehension systems that are to be developed. The power base contains the two-motor mechanism. The first step has been to design the base in a symmetrical manner so that its case may be used on the left side or on the right side. The case has been designed so that the palmar side has a form of thenar prominence that can be used for pushing on handles (e.g., lawn mowers). This prominence is covered with a soft pad that facilitates its use for pushing and also for pressing down (e.g., to hold paper) on objects. Likewise, the lateral side has a soft surface to be used for holding down objects. The power base has been given a neutral color. The base itself is gray and the rubber pads for the pressure surfaces are black. The color is designed to make the prehensor appear technical in nature and to be compatible with the prehensor finger and with the color of prostheses for black and white people.

Mechanically, a breakaway finger mechanism has been added so that the fingers may be forceably released with a force of approximately 225N. at the finger tips. The prehensor with lyre-shape adult hook fingers develops a pinch

force of 110N., has a speed of 3.0 radians per second, and will make approximately 1200 full openings and closures (closure to 70N) using a nine-volt transistor battery (80 mah) as a power source. The power base is being readied for evaluation by the Veterans Administration. Packaging of the myoelectric control electronics and of the battery remains to be completed. Several other finger designs have been developed and will be evaluated when the design of the power base is complete.

Position-Servo Control of Upper Limb Powered Prostheses

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Sponsor: VA Rehabilitation Research and Development Service

Progress — During the first phase of this development project, work has concentrated on the development of a low-power small force transducer. Several low-power (e.g., less than 1.0Ma) transducers have been developed. The first used a twin-T differential capacitor. This unit had low power and functioned well, but in tests it proved to be temperature sensitive. The second system consists of a capacitance bridge. It requires low power and appears to be suitable for practical applications. However, the supporting electronics required are more complex than desired. Pulsed (sampled) strain gauge systems have been examined but they too are complex. Other pressure transducer schemes are being investigated.

The force transducer is used as the input to the position-servo mechanism that is controlled from body joints acting upon cables connected to the powered joint and in series with the transducer. We have acquired the Hosmer Elbow, the Liberty Mutual Boston Elbow, and the Utah Elbow for clinical trials of the new controller, which is based upon the principle of extended physiological proprioception.

C. Upper Limb

2. Below-Elbow

Below-Elbow Prosthetic System

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Purpose — The objective of the project is to develop a below-elbow prosthetic system with hook/hand interchangeability and easily removable modular components. The components consist of the terminal devices, battery, electronics package, and wrist connector.

Progress — A manufacturer is now preparing this system for production. This laboratory has fabricated several prostheses using prototype components. Development work will continue with the Northwestern University Prosthetics Research Laboratory as advisor to the manufacturer. Presently a break-away device is being designed for the synergetic hook.

II. Orthotics

A. Lower Limb

[See also pg. 212]

The LETOR System for Lower Limb Support and Locomotion Assessment

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Technical Support: Sinclair Research Ltd., Cambridge, England

Purpose — A lower extremity telescopic orthosis (LETOR) has been designed to offer a simpler, lighter, effective, and comfortable stabilizing aid for paraplegia.

Progress — Over the past few years the modified versions of the LETOR have been tested with 34 paraplegic and quadriplegic patients at six rehabilitation units including EFTO in Jönköping, Sweden. During these trials, the design has proved its main advantages:

1) Easy fitting to a patient without any individual fabrication; and
2) Comfort both in the standing and relax-sitting position.

In a number of cases, when knee-joint extensors were being activated due to the telescopic action, the afferent stimulation was gradually increased to eliminate overbracing.

The extra light carbon fiber version of the LETOR is under development at the Svensk Handikappteknik AB.

Appropriate instrumented orthosis is now the research objective in extending the assessment procedure of paraplegic locomotion. The proposed method is based on the hypothesis that the level of aperiodic elements in paraplegic locomotion plotting remains in relation to the degree of reconstruction of the reflexive gait pattern generator in the spine.

Development of a Powered Orthosis for Lower Limbs

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Sponsor: Office for Life Science Promotion, Institute of Physical and Chemical Research, Agency of Science and Technology of the Japanese Government

Purpose — A powered orthosis for paralyzed lower limbs is being developed that supports the patient's body and controls lower limb movement to obtain an appropriate gait pattern. As the final goal, the powered orthosis will make it possible for a paraplegic to walk on level ground with a variable cadence, and to go up and down a staircase on appropriate command.

Progress — The first prototype of the powered orthosis has been developed. It consists of an exoskeletal frame to support the body and four electrohydraulic linear actuators to motorize hip and knee joints. A microcomputer and sensory system are used to generate and control the prescribed gait pattern. This gait pattern should be modified according to the patient's actual walking condition. A

posture sensor has been developed and is used to control the center of gravity displacement so that a stable powered walk can be obtained. It is attached to the orthosis and operates independently of environmental conditions.

Two control studies on normal subjects evaluate the effectiveness of each method: 1) autonomous powered walk by the use of posture sensor; and 2) interactive control with crutches. In the first method a stationary level walking and transient movement from the upright state to stationary walking have been realized on a normal subject by controlling the trajectory of the center of gravity. The study also verified that posture sensor powered walking is stable even in the presence of some disturbances. In the second method several essential level walking movements, such as beginning and ending of walking, stationary walking, and change of cadence have been realized and its easiness of the command has been verified. The patient can start or end the powered walking by lifting one of the crutches or by keeping them in contact with the ground longer than a certain time. The patient can regulate the cadence by changing the timing of lifting the crutches during walking.

Some additional studies are being carried out to facilitate communication between the patient and the powered orthosis. This is done through a walking state display that enables the patient to grasp how the upper torso is inclined, how the center of gravity is moving via posture, and when the feet are in contact with the ground. It allows the patient to control the powered orthosis to accomplish stable walking.

Electromechanical Walking System for Paraplegics

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Purpose — Evaluation of several functional electrical stimulation-based (FES) walking prototypes developed in other laboratories has revealed the weakness of a total FES approach in this problem. The primary concern is that simple and frequently occurring electronic malfunctions such as broken electrode lead, or loose or improperly calibrated stimulus could cause the patient to lose the upright posture, collapse, and incur additional injury. Other disadvantages included human factors, considerations such as hard-to-reach electrode sites, confusing multi-electrode configurations, and the need to suspend the patient from the ceiling for safety.

More serious shortcomings of current prototypes include the stimulation modes to induce hip flexion necessary for the swing phase. The use of induced flexion reflex could be applied to a very limited number of patients and becomes unreliable within 6-9 steps due to habituation of the nervous system to the stimulus. The use of the pendulum effect of fast release of knee flexion induced by FES results in high-impact force of the foot with the ground, high-energy losses, and the need for the patient to constantly lean forward, which is risky and uncomfortable.

Our conclusion was that although the potential of FES-induced walking is promising, current prototype systems are still substantially remote from being practical and reliable for routine clinical applications.

Progress — Our approach consisted of providing selected patients with the three necessary subfunctions for safe and reliable walking, i.e., upright posture, ipsilateral hip flexion (swing phase), and contralateral hip extension (foreward progression). Hip flexion was to be made with FES application whereas upright posture and contralateral hip extension were provided with the use of the Louisiana State University (LSU) reciprocating gait orthosis. The orthosis consists of a long leg brace with pelvic band and the support straps on the lumbar and thoracic levels for balance and stability. The two hip joints of the brace are connected with Bowden cable in such a way that hip flexion results in simultaneous contralateral hip extension. Under such circumstances, if the FES subsystem fails, the patient will lose his ability for FES-assisted walking, but will remain standing, balanced and stable.

Application of the brace to 44 paraplegics demonstrated its functional utility; several patients were able to walk without FES assistance using swing around gait. Parallel preliminary animal studies last year show that stimulation of the L-2 and L-3 roots can effectively stimulate 75 percent of the iliopsoas muscle group and induce substantial hip flexion. The results are applied toward using such a stimulation approach in human patients.

A Viscoelastic Knee Brace for Anterior Cruciate Ligament Deficient Knee

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Purpose — Damage to the anterior cruciate ligament is a major cause of knee instability in athletes. The most common procedure is the application of a knee brace, which will limit the knee's range of motion to 15 to 20 degrees of full extension. Although such a brace provides some stability in the varus-valgus and less in the rotational planes, it restricts the knee in the anterioposterior plane and causes several undesirable side effects. During athletic activity, high angular velocities in extension cause a substantial terminal impact, and subluxation and tibial rotation are avoided because of the limit imposed on range of motion; vibrations and forces are thus transmitted from the brace to the soft and bone tissue, causing unacceptable discomfort to the athlete. Furthermore, maintaining the knee at less than full extension (15 to 20 degrees flexion) effectively shortens the leg's radius from the hip joint to the foot compared with the contralateral normal leg and results in deficient gait and excessive fatigue of the quadriceps muscle group, which compensates with increased activity to lock the knee at partial flexion.

Progress — Assuming the viscoelastic properties of the anterior cruciate ligament and the absence of instability during low angular velocities of the knee in extension as in normal cadence, a speed-regulated viscoelastic knee brace was designed. The viscoelastic chamber provides constant velocity for forces in the range of four to 1200 pounds and is programmed to be activated by a cam during the last 20 degrees before full extension. The constant velocity can be adjusted over a range and should be set below the highest angular velocity that results in instability for the individual patient. Such arrangement allows full range of

motion under controlled conditions at terminal extension without the risk of instability due to subluxation and tibial rotation.

Current work focuses on improving the hinge mechanism of the brace and evaluating several offset and polycentric joints.

Load Analysis of Knee-Ankle-Foot Orthoses

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Sponsor: University of Strathclyde

Progress — Eight post-polio adult patients, one normal adult subject and ten spina bifida children have participated in the project. Although the 3 D load actions on the knee-ankle-foot orthosis (K.A.F.O.) uprights have been obtained from the custom-built transducers, interpretation of the loads at the various attachment points of the orthosis and on the orthosis/patient interfaces is complex due to the statically indeterminate load system. To facilitate in the analysis, shear force transducers to measure the forces at strap attachment points have been added.

The short-term aim of the project is to provide data on the loads on the orthosis for design purposes. The patient activities under investigation are: walking on a straight line, walking round a double bend, walking round a U-shaped path, stepping up and down a low platform, and ascending and descending stairs and slopes. So far the maximum values of the critical bending moments on the K.A.F.O. uprights were found to be 33 Nm in the anterioposterior direction (while descending a slope) and 15 Nm mediolaterally (while walking around a double bend).

Foot and Shoe Interface Study

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Purpose — Peripheral neuropathy associated with diseases, such as diabetes mellitus, often causes severe deficiency in transmission of sensory modalities in the lower extremities. Such losses impair the protective mechanisms and render the extremities vulnerable to the effects of applied forces of every day ambulatory activity. This not only results in skin ulcerations but may also cause hyperemia and inflammation secondary to trauma. Many diabetic patients with foot ulcers are seen at the VA Medical Center and often there is difficulty in achieving healing because means to reduce repetitive plantar pressures are inadequate. Required are criteria for prescribing interface materials and means for evaluating effectiveness of materials chosen.

The hypotheses in this study are:

1) Plantar pressure ulcers in hypo or insensitive feet may be effectively treated by use of appropriate interface materials.

2) Physical properties appropriate for the selection of interface materials can be determined.

3) Adequacy of static load distribution properties of an interface material can be determined by use of a barograph.

Progress — During clinical testing, patients with established findings of peripheral neuropathy, diabetic or non-diabetic, are seen periodically to monitor condition of the insole. For those with ulcerations of the plantar surface the width, breadth, and depth of the ulcer are measured and recorded. Patients' weight and ambulatory habits are noted and the thickness of the used insoles are measured at points of maximum compression set. If the thickness is 50 percent or less than the original thickness, the insole is collected and a new one issued. Vibratory perception thresholds on the foot and legs of patients seen for the first time are mapped. Attempts are made to refine definition of the "at risk" boundary among patients. Appropriate plantar barograms are obtained. For patients with severe ulcer areas, total contact casts to unload the ulcer area during ambulation are used. After the ulcer heals and scar tissue matures, thick heat molded insoles and sandals are used during ambulation. For selected patients composite insoles, consisting of a heat molded element cemented to an open cell noncompression set material such as PPT to SPENCO to evaluate their efficacy, are issued.

During laboratory testing, time-related and nontime-related properties of a variety of candidate materials for insoles are evaluated. Recovery properties of collected insoles are determined.

Preliminary Results — Method of treatment influences success in patient care. For the not "at risk" patients, unmolded, small-cell foamed polyethylene insoles are satisfactory. Issuing four sets for daily change allows partial recovery from compression set. The "at risk" patients require two-stage treatment: the total contact cast during ulcer healing followed by thick heat molded insoles and sandals while scar tissue matures.

Future Plans — Since this project is nearing completion, the plan is to continue collection and analysis of data toward the objective of defining prescription criteria.

San Francisco Molded Shoe

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Purpose — Research continues on the development of a molded therapeutic shoe. The purpose of this work is to lower both fabrication costs and time as well as providing improved biomechanical molded footwear for patients with diabetes mellitus. Many diabetic patients with foot ulcers have had to undergo foot and leg amputations as a result of the prolonged manufacturing process required for custom footwear. Additionally, the positioning of the foot during the traditional casting method has not been standardized and thus optimum foot support, accurate arch height, and biomechanical efficiency have not been achieved.

Progress — The research and development thus far has been directed at the following:

1) Development of a casting platform to assist in accurate positioning of the foot to standardize and assure reproducibility of the molding process.

2) Development of an electronic ultrasound measuring instrument which assists in obtaining the neutral position of an individual's subtalar joint. This is achieved by measuring the internal and external rotation of the leg. This instrument will be used in the casting phase of the shoe development.

3) Designing a molding system to accept polyurethane foam for different shaped feet and lasts.

4) Developing a system for low cost shoe fabrication.

A casting platform has been constructed with the intention of having patients in a seated position while having the thigh, leg, and foot maintained at 90 degrees. A constant force is applied from the plantar surface of the foot. The incorporation of an adjustable chair, thigh restraints, and foot plate has allowed reproducible positioning.

An ultrasound measuring instrument has been developed that measures transverse plane leg rotation. The internal and external leg movement that accompanies supination and pronation of the foot is measured by ultrasound waves transmitted to leg-mounted receivers. An electronic display of the movement has been incorporated into the instrument. The measured range of motion is evaluated and the foot is then placed in its neutral position during casting guided by the instrument.

A polyurethane resin casting material is being used to obtain the accurate shape of the foot and ankle. Once the exact replica of the foot has been obtained, the cast is removed and modified. A vinyl barrier is created around the last and the polyurethane is injected into this mold just after a shoe upper has been attached to the last. The midsole and upper are then removed and a sole adhered. A sandal design has been selected as the first shoe to be created and tested by patients.

Patients will be characterized as to their neurological, vascular, foot structure, and biomechanical status. This will be accomplished through ultrasound technology, doppler, aesthesiometry, thermography, biothesiometry, physical examinations, as well as other noninvasive methods. Once stratified into risk groups, selected patients will be placed into a San Francisco Molded Shoe of different styles (e.g., sandals, oxfords). The patients will be monitored and evaluated as to the therapeutic effectiveness of the shoe. The shoes will likewise be evaluated relative to wear characteristics, design, patient acceptance, and biomechanical efficiency.

B. Spine

[See also pgs. 202, 206]

Analysis and Design of Optimal Halo Systems

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Progress — Suspension or traction halos applied to patients with cervical fractures are fairly effective in stabilizing the spine in the early period of application. Screw loosening, normally seen after the initial period, is followed by infection and removal of the halo.

We studied the role of the following factors in improving the bone-screw interface: screw length; screw diameter; screw thread-turn density; and, angle of rotation in suspension halo.

Computer simulation showed that a short screw of larger diameter with high thread-turn density can improve the bone-screw interface substantially. Some 40 percent to 72 percent cumulative reduction in shear stress, torque, and compressive force is possible. The data obtained are evaluated from the realistic standpoint to provide guidelines for the design of an improved halo system.

Retrodisplacement and Spondylolisthesis — Brace Treatment

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Purpose — This project proposes to study the effect of bracing on homogenous low back pain patients classified by the presence or absence of either excessive anterior or posterior translation on flexion-extension radiographs.

Progress — Patients with back pain of four weeks' to one year duration are classified into four groups: retrodisplacement — worse in extension; retrodisplacement — worse in flexion; spondylolisthesis (of any type); and, normal translation. Each classified group is randomly assigned to flexion, extension, or non-specific education treatment. Flexion and extension treatments include specific education and exercises as well as brace treatment.

To accomplish these specific aims, the following hypotheses will be tested:

1) Patients with radiographic retrodisplacement (reverse spondylolisthesis) and low back pain of greater than four weeks' duration who demonstrate greatest displacement on an extension radiograph will respond more favorably to a flexion orthosis than three other patient groups: (a) those with the same X-ray findings treated with an extension orthosis, (b) those with the same X-ray findings treated with nonspecific low back education, and (c) patients with normal radiographic translation treated with the same disregard orthosis.

2) Patients with radiographic retrodisplacement and low back pain of greater than four weeks' duration who demonstrate greatest displacement on the flexion radiograph will respond more favorably to an extension orthosis than three other patient groups: (a) those with the same radiographic findings treated with a

flexion orthosis, (b) those with the same radiographic findings treated with nonspecific low back education, and (c) patients with normal radiographic translation treated with the same extension orthosis.

3) Patients with radiographic anterodisplacement (spondylolisthesis of any type) and low back pain of four weeks' duration will respond more favorably to a flexion orthosis than three other patient groups: (a) those with the same X-ray findings treated with an extension orthosis, (b) those with the same X-ray findings treated with nonspecific low back education, and (c) patients with normal radiographic translation treated with the same flexion orthosis.

4) The response to either a flexion or extension orthosis can be predicted by: (a) radiographic measurements, and (b) clinical symptoms and signs, or psychosocial variables.

III. Total Joint Replacement and Other Orthopaedic Implants

A. General

Development of Biologic Cement for Fixation of Skeletal Implants

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Purpose — The objective of the project is the development of biologic cement substances that can be used to stabilize artificial implants in bone and joint replacement surgery and to augment bone growth. Most of the current investigation is performed in animals. The work has direct clinical application in the fitting of porous coated prostheses in bone deficient elderly patients and in surgery involving failed prostheses.

Progress — Several specific substances have been tested for their short- and long-term efficacy in the fixation of porous coated implants. Tricalcium phosphate, demineralized bone matrix, and milled autogeneous bone graft have been tested and evaluated for stabilizing effect. Among these, demineralized bone matrix was found to be the most effective, probably because of its osteoconductive and osteoinductive properties.

In general, the methods involve the use of biologic cement mixed with a biologic binding substance (whole blood or blood plasma) and packed around the porous implant in an over-reamed intramedullary canal of the femur. The control femur on the opposite side is implanted with a similar porous rod but without the cementing substance. The union of the implant-bone composites are evaluated serially using radiographs, thin section histology, and mechanical pull-out tests.

Currently, work is in progress to compare osteoinductive properties and biocompatability of autoclaved and freeze-dried donor bone powder with decalcified bone matrix and autogeneous milled bone.

A series of experiments are also in progress for evaluating combinations of materials that are osteoconductors (acting as scaffold for bone growth) and osteoinductors (materials stimulating natural bone production). Tricalcium phosphate, an osteoconductor, is being compared to: 1) demineralized bone that is osteoinductive; 2) a protein extract of demineralized bone with osteoinductive character; and 3) demineralized bone enhanced with the protein extract.

Preliminary Results — Results thus far indicate a nearly three times increase in the pull-out strength of a donor-bone stabilized prosthesis when compared to the unstabilized control at 6 weeks post-implantation. The effect of long-term (24 weeks) strength of the milled autogeneous bone graft also is being studied. Early results, however, show only a modest improvement on the stabilized side over the

control, suggesting that the stabilizing effect of this biologic cement is more pronounced early and the control and cemented side approach the same pull-out strength in the long term.

A previous hypothesis indicated that cortical bone produced stronger interface between implant and bone than cancellous bone ingrowth. Currently, quantitative analysis of AP and ML X-rays is conducted to record bone and implant relationships in the control, over-reamed but un-biocemented femurs. From measurement of bone and implant diameters an index of cortical nearness is calculated for each specimen and related to the pull-out strength. The results show stronger bone ingrowth when the cortex is nearer to the implant, confirming the cortical influence on growing bone strength.

Vacuum Mixing of Acrylic Bone Cement

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Purpose — Since the introduction of poly(methylmethacrylate) in 1960 for use as a bone cement to fix total joint prosthesis, such as total hips and total knees, there has been virtually no change in the basic material nor its method of preparation. Approximately 200,000 total joints are currently being implanted each year with a great deal of success. However, since long-term failures do occur and, when this happens, the bone cement is often implicated in the aseptic loosening of the component parts of the total joints. A stronger, tougher, more fatigue resistant cement is needed. Since under the present drug laws the introduction of a cement of new chemical basis could be very costly, it seems logical to attempt to optimize the physical properties of the current acrylic bone cements through fabrication, processing, and handling modifications.

The present work will describe processing the admixture of cement powder and liquid under a partial vacuum in order to remove much of the inherent porosity and thereby significantly improve the mechanical properties over cements prepared by the conventional mixing techniques of hand spatulation.

Progress — Initially, large amounts of air lying between the powder particles appear necessary to facilitate wetting when combining with liquid. Additionally, air can be folded into an admixture during stirring. While other sources of porosity can be controlled (e.g., prevent boiling of monomer during exothermic polymerization by using sufficiently small specimen cross-sections; avoid entrapment of air during specimen fabrication by syringe injection and properly vented molds), the original powder air and the mixing air must be removed with a device. Tests have shown significant reductions in porosity using a high vacuum device, but the high mixing speeds employed generated excess heat that shortens the cement working time. Other tests have shown reduced porosity through the use of centrifugation.

The present device consists of a 550 mm Hg vacuum bowl with a one revolution per second blade designed to lift bubbles to the surface while avoiding further enfolding of air. Significant differences in porosity are obtained with three different mixing techniques: regular, centrifuge, and vacuum. Densities were

determined from weight and volume measurements of three groups of 40 specimens fabricated in compliance with ASTM F451-76 molds for six mm diameter times 12 mm mechanical test specimens. The porous defects then were analyzed by sterologic computer programs. Essentially, when compared to regular mixing, centrifugation removes the larger pores while vacuum removes most of both of the large and small pores. This observation also may serve as a basis for the significant differences in mechanical properties. The uniaxial tensile fatigue specimens were machined into hour glass shapes, and the stresses represented the maximum in a zero to maximum sinusoidal cycling program. At these high stress levels, vacuum and centrifuge mixing produce vastly improved fatigue lives over regularly mixed cements. Lower stress, more clinically relevant fatigue tests are now in progress.

Examination of Implants by Photoelastic Techniques

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Sponsor: Musgrave Park Hospital, Northern Ireland Prosthetics, Orthotics and Aids Service

Progress — The photoelastic technique is being used to examine the stresses in surgical implants. These stresses in femoral implants have been examined in relation to implant position and support conditions. Stresses in bone cement have been examined around various cross-sectional profiles of femoral stem. There also has been an examination of the stresses in bone, which were compared with trabecular structure and bone strength.

It is proposed to extend the study to boundary conditions at the bone/cement/prosthesis interfaces. The method has been found to provide a useful additional tool for the analysis of prosthetic implants and their design.

Investigation of the Bone/Bone Cement/Implant Interface Formed by Total Joint Replacement

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Purpose — The objectives of these projects are to identify the causes of late loosening of total joint replacement components by examining several aspects of the interface system.

Progress —

1) Investigations of the factors affecting the mechanics of bone/bone cement interface failure — A paper detailing the results of experimental tensile tests on the interface has been published in the Journal of Orthopaedic Research. Complete effort has not turned towards quantifying the interface using a fatigue/fracture methodology that is hoped to prove more clinically relevant. The interface is studied in four point bending cyclic fracture mechanics tests. Attempts are being made to measure crack propagation through the interface as a function of stress intensity factor, cement penetration, and bone strength. Two recent abstracts have been published detailing initial results (1985 ASME Biomechanics Symposium, 1985 ORS Meeting). The study uses published interface crack models developed at Northwestern. Specimen testing continues on a variety of

interface formation states. When testing is complete, a comprehensive report on the subject will be prepared.

2) Investigation of mechanical, histological, and load transfer properties of the soft interface tissue commonly found at the bone/cement interface — A paper detailing results of this project has been published in the Annals of Biomedical Engineering. No further work in this area has been done.

3) The testing of the interface between various metal surface preparations and bone cement via a fracture mechanics methodology — No progress has been made on this project although its implementation is still planned. Specimens will be tested using four point bending cyclic fracture mechanics tests.

Orthograft Large Granular (LG) Study

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Progress — Orthograft is a large granular synthetic bone graft substitute consisting of calcium phosphate. Under protocol, it is to be utilized for the filling in of voids within bones. This has been used in dentistry.

To date, we have not had a surgical case with the indications for the use of orthograft in the institution. However, we intend to keep the protocol in effect and in anticipation of cases that will be suitable for this study in accordance with the original protocol.

Implant Fixation by Post-Insertion Pressurization of Polymethylmethacrylate

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The purpose of this project is to assess the premise that sustained high pressure applied to polymethylmethacrylate (PMMA) bone cement will increase the strength of the cement and the bone cement interface.

Progress — A specially designed injection system was developed with which cement could be injected into human cadaver femora with pressures up to 100 PSI and maintained until late in the polymerization (i.e., eight to twelve minutes after mixing). The proximal portion below the lesser trochanter of paired human cadaver femora were used. Simplex P (Howmedica) was injected into one and low viscosity cement (LVC — Zimmer) was injected into the opposite of the pair. Shear strength of the bone-cement interface was determined by preparing 10 mm times 5 mm specimens of cortical bone and cement which were sheared to failure in a specially designed shear testing clamp with a 1.5 mm window centered over the interface using a servohydraulic testing (Matco) machine at a deformation rate of 0.5 mm/second, strain rate of 0.33/second. The shear strength of the cement alone was determined in identical fashion. Penetration of the cement into bone was determined by first photographing cross-sections of the femora and digitizing at 10X magnification the cortical area. The slices then were placed in a 10 molar hydrochloric acid solution. The bone was partially dissolved leaving the

medullary canal cement and cortical cement spicules intact. The specimens were then photographed a second time and digitized for the cortical cement area.

In order to provide clinical relevance, a single pair of femurs was prepared with contemporary techniques, the two cements were injected with a clinically used cement gun and "pressurized" for 10 seconds before a Charnley-type total hip prosthesis was inserted. The mean bone-cement interface shear strength was 3.18 ± 2.36 MPa for LVC and 2.85 ± 1.86 MPa for Simplex P.

Twelve pairs of femurs were divided into four groups of three each and pressurized at 20, 40, 60 and 80 PSI. There was a progressive increase in the bone-cement shear strength with increasing pressure up to 60 PSI but no further increase at 80 PSI. More importantly, no significant difference was found between Simplex and LVC. The mean strength at 20 PSI was approximately 7.5 MPa and at 60 PSI, approximately 11.5 MPa. The shear strength of the PMMA alone ranged from 50 to 60 MPa but there was no significant difference with increasing pressure beyond 20 PSI and no difference between cements.

There was relatively little cancellous bone in the portions of the femora studied but, where present, penetration of the cement was nearly 100 percent at all pressures. With both cements, cortical penetration of LVC cement was significantly greater than with Simplex at all pressure levels and, at 80 PSI, approached 80 percent of the cortical area.

It was concluded that:

1) Sustained pressurization of PMMA in human cadaver femora increased the shear strength of the bone cement interface by a factor of two to three magnitudes over conventional techniques.

2) There was no significant difference in interface shear strength between Simplex P and LVC cements.

3) Penetration of LVC cement into cortical bone was significantly greater than the penetration of Simplex but was not associated with an increase in interface shear strength.

Intermolecular Bonding and Microphase Separation in Polyurethane Block Polymers

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Sponsor: National Science Foundation, Bioengineering and Research for the Handicapped Program

Purpose — This research deals with structure property relations of segmented polyurethanes and related multiphase elastomers. The researchers are involved in the synthesis of novel polyurethanes and their characterization by small angle X-rays scattering, infrared spectroscopy, and a variety of other methods involving thermal, mechanical, and viscoelastic analysis. Polyurethanes are well known for their outstanding physical properties such as unusually high strength, fatigue resistance, abrasion resistance, and impact absorption characteristics. They also can be prepared in quite pure form and free from the typical vulcanization additives other rubbery systems require for their care.

Progress — A major application of these high performance elastomers is as biomaterials. Such uses of polyurethanes include the more routine, such as orthodontic mouthpieces and elastomeric support hose, to the more frontier areas

of restorative surgery. These latter applications include a wide variety of uses which range from plastic surgery (artificial ears, hands, and miscellaneous body parts), treatment of burns (artificial skin during wound healing), orthopaedics (support materials, finger joints), vascular surgery (artificial blood vessels), general surgery (catheters, balloon catheters, artificial trachea, heart assist devices), to the total artificial heart. Currently, the researchers are carrying out the synthesis and characterization of silicone rubber-polyurethane block polymers and ultra-violet or electron beam curable polyurethane oligomers. Silicone polyurethanes may find ultimate use as a material for plastic surgery reconstructions, possibly as artificial ears or skin coverings. The researchers also believe the radiation curable polyurethanes may be considered as new generation materials for lightweight bone healing cast applications.

The research on polyurethanes as biomaterials, which is partially supported by the National Institutes of Health, focuses mainly on understanding the mechanism of artificial surface-induced thrombosis. Through this research, the investigators hope to learn more about the process of blood clotting on polymer surfaces and to design materials which remain patent when serving as 5.0 mm or smaller vascular grafts. Success here would significantly reduce lower leg amputations in those patients suffering from various vascular disease states. This aspect of the research would act to prevent the necessity of creating a state of greater handicap (by amputation) for a small fraction of elderly patients with severe circulatory disorders.

Diagnosis of Loose or Damaged Total Joint Replacement (Human)

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Sponsor: National Institutes of Health

Purpose — The need exists to correctly diagnose mechanical degradation of total joint replacements. The efficacy of *in vivo* joint monitoring by means of acoustic emission has been demonstrated. To further develop the technique of *in vivo* monitoring, the acoustic emission waveform characteristics will be analyzed using correlation plots and together with the attenuation results will be used to optimize the electronic equipment through proper choice of waveform filters.

Progress — The development of acoustic emission monitoring requires continuation of an ongoing program to monitor patients from the Hip and Knee Clinics of The Hospital for Special Surgery who are clinically considered to be at high risk of mechanical failure. Correlation of acoustic emission results with other clinical findings will provide a basis for clinical interpretation of acoustic emission results. The mechanisms which generate acoustic emission will be further examined.

Acoustic emission resulting from failures in implant materials such as bone and polymethylmethacrylate did not correlate well with results from *in vivo* monitoring. Therefore, the contribution of interface failure and cancellous bone failure as the most probable sources of acoustic emission will be investigated with *in vitro* experiments and finite element analysis. Composite models will be

monitored during loading. Specialized finite element analysis capabilities aimed at determining failure loads and locations in interfaces will be used to correlate acoustic emission results (both experimental and clinical) with analytical predictions.

Ultrasonic Study of the Cement-Cancellous Bone Interface (Cattle, Human)

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Sponsor: National Institutes of Health

Purpose — Most current designs of total joint replacements make use of bone cement to fix the artificial joint component to the bone. Prostheses primarily fixed to the porous inner part of the bone, called cancellous bone, sometimes fail after several years of use, causing much suffering to patients and a high financial cost for additional surgery to remove the failed prosthesis. Loosening of the prosthesis has been indicated as a primary cause of mechanical failure. Stress analysis of prosthesis designs is carried out numerically using the finite element method. To make use of this method, accurate three-dimensional stiffness data are needed for all components of the prosthesis-cement-bone structure. It has been suggested that deeper penetration of the cement into the pores of cancellous bone will enhance the success rate of the prosthesis. This idea creates a layer of a cement-bone composite, the properties of which are not known.

Progress — In this study the elastic constants of the cement-bone composites will be determined by a pulse transmission ultrasonic technique. Specimens of bovine and human cancellous bone will be cut in the form of 5 mm cubes from larger segments of cancellous bone, after filling the pores of the bone with bone cement. The composite material thus obtained will be assumed to be orthotropic and all nine elastic constants will be determined. This information is expected to be of direct use in finite-element analyses of orthopaedic implants.

Mechanisms of Orthopaedic Implant Loosening (Rats)

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Sponsor: National Institutes of Health

Purpose — Orthopaedic joint reconstruction with an implanted artificial prosthesis is an increasingly common surgical procedure. Unfortunately, at least seven percent of patients receiving such prostheses will experience implant loosening and, ultimately, failure within five to seven years of surgery. The precise reasons for this high rate of failure are unknown. However, histological studies of the tissues surrounding loosened implants suggest that mononuclear phagocytes (MO) and foreign body giant cells (GCs) play an important role in the rejection process. Specifically, these cells, which seem to be recruited by implant derived particles, are believed to be directly responsible for resorbing the bone immediately surrounding the implant, and are perhaps instrumental in the development of an inappropriately thick connective tissue capsule between the implant and the supporting tissue. However tenable is the hypothesis regarding the role of MOs and GCs in implant loosening, it is based upon histological observations and is therefore, at best, intuitive.

Progress — The aim of the present proposal is to directly assess the potential of MOs and GCs to affect those changes believed essential to prosthetic loosening, particularly when exposed to implant derived materials. These studies will focus on use of *in vitro* assay systems, established in this laboratory, with which we have previously documented the ability of MOs to resorb vital and devitalized bone, demonstrated that bone matrix degradation can be precisely quantitated, and shown that MO- and GC-mediated bone resorption can be regulated by systemic bone-seeking agents (e.g., cortisol) and by, as yet, undefined factors released by other cells.

In this application, we propose to extend the use of these techniques and experience, to:

1) evaluate the action of implant materials on MO- and GC-mediated bone;

2) identify the enzyme(s) responsible for bone collagen degradation by MO and GC, and explore the regulation of this enzyme(s) by implant materials;

3) study the potential of MO, GCs and endothelial cells exposed to implant derived material to modulate (stimulate) bone resorption by other cells, including osteoclasts; and

4) establish whether phagocytosis of implant particles by MOs promotes the release of agents capable of stimulating giant cell formation and fibroblast proliferation.

Orthopaedic Implant Retrieval and Analysis

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Sponsor: VA Rehabilitation Research and Development Service

Progress — The implant retrieval and analysis research program continues to collect orthopaedic hardware from Veterans Administration-affiliated medical centers. To date, 5,235 patient records have been accumulated. During 1984, 656 devices were inserted in four VA-affiliated hospitals and 220 implants were removed routinely or due to cause-related reasons.

Presently, the clinical performance, corrosion characteristics and metallurgical properties of retrieved femoral and total knee prostheses are being evaluated. These properties have recently been examined in 82 retrieved bone plates which were *in situ* for periods of one to 169 months. Fifty-one of the 82 plates were removed for cause-related reasons, while only 24 were removed on a routine basis. (The removal reasons for seven plates were unknown). Stereomicroscopic examination revealed that over 89 percent of the recovered implants displayed some degree of pitting, crevice, and/or fretting corrosion. Statistical analysis revealed that metallurgical properties correlated significantly with all types of corrosion. This evaluation suggested revision of current ASTM standards to improve the corrosion resistance or orthopaedic implants.

Other recently completed studies evaluated the clinical performance and metallurgical characteristics of retrieved hip plate devices and intramedullary rods. The 61 hip plates studied included two commonly used designs: the Jewett nail-plate and the Richards screw-plate. These devices were *in situ* for two to 156 months, yet only 10 percent were removed on a routine basis. Our data suggested that surgeons consider these devices to be permanent implants with removal undertaken only for causative factors. No statistically significant differences were

found between the metallurgical and corrosion properties of the two designs studied, however four devices of each design were out of ASTM specification. Also, four of the Jewett devices fractured *in situ*.

Similar evaluations were made on 16 A-O intramedullary rods. Cracking and/or fracture was observed in four of the 16 rods. This study revealed that structural and material characteristics were responsible for implant mechanical failures, thus warranting improvements in fabrication techniques. Also, our data suggested careful assessment of a painful IM rod and routine removal after fracture healing.

A clinical analysis of 28 retrieved Harrington rods also has been completed. Fifteen rods fractured *in situ*, yet our data revealed that material defects were probably not contributory to the implant failure. Emphasis on attention to surgical detail in order to obtain early graft healing and solid hook placement was suggested.

Evaluation of Total Joint Loosening Using X-Ray Photogammetry

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Progress — Our research has developed a method that can accurately measure the distance that a prosthetic component settles after it has been placed in the bone. The equipment required to perform such measurements include: 1) a device to insert stainless steel landmarks into the components and surrounding bone; 2) a jig to position the X-ray annodes with respect to patient; 3) a calibration cage which holds the X-ray cassettes in proper alignment to the X-ray beams for optical linear encoders for measuring the X/Y coordinates of each landmark of the X-rays; and, 4) software for determining displacement of components with respect to bone.

This past year the software has been further refined and simplified. We continue trying to interest manufacturing companies in bringing this system to a commercial level.

B. Hip

Load Transfer of Non-Fixed Close-Fit Femoral Stems (Sheep)

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Sponsor: National Institutes of Health

Purpose — The long-term results of conventional cemented total hip replacement show a deterioration with time, such that beyond 10 to 15 years the failure rate may rise to as high as 40 percent. In younger more active patients, a failure rate of 50 percent at only five years has been reported. Revision surgery is difficult, most often leads to a result which radiographically at least will be much shorter-lived than the primary case, and sometimes involves serious bone loss jeopardizing the future viability of the entire reconstruction. Neither surface replacement nor bone ingrowth is seen as the answer. However, there has now been 30 years of clinical

experience with non-cemented femoral components such as the Austin-Moore. While the failure rates are not lower than with cemented stems, a large proportion of the failures are associated with acetabular protrusion. In many other failures a poor fit of the stem in the canal is implicated. The loss of bone associated with failure and removal is generally much less than with cemented stems.

Progress — It is proposed that a stem designed to be a close fit in specific load-bearing areas, a "Close-Fit Stem," may well provide the answer to reliably obtaining a durable result. Our aims are to determine the required sizes and shapes of such a stem and to test the fit and the load transfer *in vitro* and the biological response *in vivo*. Color computer graphics will be used to model the shape and size ranges of the femoral canal while a stem fit program will determine the number of stems required to specified accuracies. Closeness of fit will be tested on actual bones using sectioning techniques. Bone strains and stem-bone shear movements will be compared for cemented stems, the Austin-Moore, a metallic close-fit stem, and close-fit stems with a polymeric coating. These designs will be tested in an ovine model to observe the differences in bone response and to test whether the bone appears to adapt more satisfactorily to the Close-Fit Stems. For possible augmentation of closeness of fit and encasement of a Close-Fit Stem with new load-bearing bone, osteogenic stimulating demineralized bone powder (DPB) will be used as a filler. This work will provide valuable data of the viability of a Close-Fit Stem. If such a scheme is successful, it will have an invaluable place in hip surgery and have far-reaching applications even in the older population.

Skeletal Aging and Disease in Failure of Hip Surface Replacement

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Purpose — Surface Replacement Hip Arthroplasty (SRHA) in comparison to Total Hip Arthroplasty has the advantages of replacing the diseased hip surface while preserving normal bone stock and maintaining more normal physiological bone loading patterns. This provides an easier method for replacement of failed implants and decreases the occurrence of deep infection in the femur subsequent to surgery. However, these advantages have been offset by high failure rates mainly due to early loosening of the femoral and/or acetabular components.

The objectives of this project are to determine causes of early loosening in SRHA and relationships between these causes and skeletal aging and disease. The possible causes for SRHA failure include: 1) poor initial fixation due to inadequate operative technique and instrumentation; 2) bone necrosis secondary to disruption of the blood supply; 3) inadequate initial bone strength; and, 4) bone remodelling due to stress redistribution related to prosthesis design or to processes of aging and disease.

Progress — Femoral head and acetabular specimens obtained from osteo and rheumatoid arthritic patients in conjunction with total hip replacement from cadavers are subjected to one or more of the following procedures:

1) Mock SRHA is performed on the femoral head and the strength of mechanical fixation is determined using torsional failure tests.

2) Radioisotope scans and tissue scintillation counts are performed on THR femoral heads and necks obtained from patients injected with T-99m directly after capsular stripping. These techniques are used to localize acute changes in femoral head vascularity due to disruption of the reticular blood supply.

3) Femoral head, acetabular and iliac create specimens are sectioned and analyzed via mechanical tests or bone histomorphometry. These tests are used to determine and compare the mechanical, structural, and physiological properties of diseased and normal hip bone. The results of these analyses will be mathematically modeled to determine the ability of underlying hip bone to chronically support current SRHA components.

The data obtained from this study will be used to determine the viability of SRHA and if possible, to design improved components and techniques.

Preliminary Results — The major accomplishments of this study to date are:

1) The capabilities of the new Orthopedic Histomorphometric Laboratory to perform hard tissue histology in accord with the protocol have been enhanced by equipment acquisition using non-VA funds. This new equipment includes a diamond wire saw for cutting thin sections, a precision histological grinder capable of reducing large plastic sections to 15 mu, and a microradiographic unit for bone density analysis.

2) Tetracycline-based histomorphometric analyses are now being performed on hip bone samples.

3) Mechanical compressive testing techniques for analysis of femoral head sections have been developed and verified. These techniques provide reproducible three-dimensional maps of femoral head bone mechanical properties. Tests are being completed on selected specimens.

4) In preparation for the use of radioisotope-based determination of femoral head vascularity in THR patients, a preliminary study was completed. Technetium-99m (T-99m) HDP and MDP-based bone scanning and tissue scintillation counting techniques were applied to dogs subjected to THR in order to evaluate the ability of such techniques to measure changes in femoral head vascularity due to surgical stripping of the hip capsule. Results from these studies indicated that for the dog capsule disruption reduces blood flow to the surface bone of the femoral head. The scans and counts provided sufficient data to map the location of vascular compromise. These preliminary results in the dog support the use of such techniques for vascular assessment in THR patients.

Principle project activities for the next few months will be continued collection and processing of specimens and analysis of data.

Porous Coated Dual-Lock Cementless Hip Clinical Investigation

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — This study uses a standardized operative protocol for the implanting of porous metal total hip components. Periodic analysis of radiographs and of function is used to document the results. The objective of biologic fixation is to obviate a high failure rate seen in cemented systems.

Progress — To date we have implanted about 50 of these hips with no failures through loosening or infections. One hip dislocated and was reduced closed.

Recovery and function equalled the old cemented systems with operative time reduced. Late infection is much less. Early infection was probably about the same or less as in the cemented system.

Preliminary Results — The conclusion to date is that this system is superior to the cemented system in at least three ways: 1) reduced operative time; 2) fewer late infections; and 3) reduction in mechanical failure. No unique complications have been noted. Bone remodeling may be enhanced. The program is successful and should be a continuing study.

The Mechanical Properties of Porous Coated Orthopaedic Alloy

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Purpose — The porous metal coating applied to a solid substrate has been shown *in vivo* to offer advantages over current methods of implant fixation. However, these advantages may be lost in devices requiring a sintering heat treatment to apply the porous coating. In our studies to date, uncoated Ti-6A1-4V orthopaedic alloy was found to have an endurance limit of 605 MN/m^2. The application of a porous coating decreased the endurance limit by approximately 77 percent, and when the uncoated substrate material was heat treated to the same temperature as the porous coated samples, a degradation of approximately 34 percent was observed. The difference was that the porous coating acted as a notch.

The reduction of fatigue properties by the heat treatment is due to the transition from the as-received equiaxed microstructure to the lamellar structure upon sintering. This lamellar structure has been shown to have inferior fatigue properties relative to the equiaxed structure. In the present study, microstructural analysis was performed on three different post sintering heat treatments of Ti-6A1-4V in an attempt to improve the fatigue properties. The heat treatments investigated provide microstructures somewhat different from the original sintering heat treatment. These heat treatments may help in resistance to crack initiation and propagation during the cyclic loading of porous Ti-6A1-4V orthopaedic devices and thus result in improved fatigue properties.

The microstructures obtained from the heat treatments were lamellar, coarse acicular, and fine acicular. Mechanical properties such as yield strength, ultimate tensile strength, percent elongation, and hardness were investigated and compared to those of the as-received equiaxed structures. As expected, the equiaxed structure exhibited the best properties: yield strength of 965 MPa, ultimate tensile strength of 1140 MPa, elongation of 13.50 percent, and Rockwell Hardness C of 32.90; whereas the lamellar structure produced the poorest properties: yield strength of 824 MPa, ultimate tensile strength of 954 MPa, elongation of 5.10 percent, and Rockwell Hardness C of 26.20. The acicular microstructures displayed mechanical properties that ranged between those of the equiaxed and lamellar structure. Overall, the fine acicular structure was stronger than the coarse acicular structure.

The Efficacy of Radiolucent Low Modulus Total Hip Surface Replacement

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Purpose — The objective of this project is to investigate the potential of using a radiolucent low-modulus surface replacement as a prosthesis for the hip. This work is a bone remodeling study in that a comparison of the cancellous bone under a carbon femoral surface replacement is to be compared to the normal cancellous bone in the contralateral hip. In addition, the bone under a carbon femoral prosthesis is to be compared directly to the cancellous bone of the contralateral femoral head which has been resurfaced with a cobalt chromium prosthesis of a much higher modulus.

Progress — At this point all of the unilateral carbon replacements have been retrieved and are undergoing quantitative trabecular stereology. All of the bilateral replacements have been implanted and will have been retrieved by January, 1986. These then will undergo histologic examination and quantitative trabecular stereology. In the meantime, finite element studies of the femoral head with the carbon and with the cobalt chromium prosthesis are underway and preliminary results have been obtained that must eventually be compared to the results of the quantitative trabecular stereology.

Computerized tomographic scanning of the unilateral and normal control hips has been performed. The data obtained from these studies also will be compared to the results of the quantitative trabecular stereology for those animals with a carbon surface replacement.

In an attempt to improve the finite element studies, an algorithm has been developed for use on CT scan data to define trabecular pattern so that this information may be included in finite element modeling. Presently, work is progressing on using CT scan data to generate finite element meshes. It is anticipated that the histologic studies will be completed early in 1986.

Total Hip Biotelemetry

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Purpose — The objective of this project is the design and development of a special total hip femoral component that contains within it a miniaturized biotelemetry system capable of broadcasting signals received from strain gauges mounted inside the neck of the prosthesis. The prosthesis will be inductively powered by an external coil thus eliminating the need for internal batteries or connecting cables. This is a collaborative effort involving the Research Service of the Wadsworth VAMC, the UCLA Division of Orthopaedic Surgery/Biomechanics Research Section, and the Jet Propulsion Laboratory.

Progress — Since the last report, several design changes were necessitated to accomplish the specific objectives. The ball-neck unit was successfully broached with eight slots in the inner periphery of the neck. Eight active and four dummy semiconductor gauges were bonded in these slots as per a preliminarily approved attachment procedure. The dummy gauges are mechanically isolated from the

prosthesis with a slab of similar material and RTV Silastic. Static load tests were conducted on this unit by applying a 200-pound bending force acting at 90 degrees to the neck axis and the change in resistance of each of the gauges was recorded. This test was repeated for each 45 degree rotation of the unit about the axis of the neck. Axial force tests were also performed by applying 825 pounds force to the top of the ball along the axis of the neck.

Both the bending and axial tests indicated that the active gauges behaved as predicted. However, the isolated dummy gauges were changing by as much as 20 percent of the active gauge change. The dummy gauge attachment procedure was modified to increase the thickness of the carrier plate and the RTV layer. The tests were repeated with the modified gauge attachment procedure and the dummy gauge outputs were found to be less than 1 percent of that recorded for the active gauges. The remaining prosthesis housings were then broached and the gauges attached according to the modified procedure.

Due to questions concerning the biocompatibility of the material proposed as a secondary seal and the lack of commitment by the manufacturer to guarantee its biocompatibility, it was decided to include a primary glass feedthrough seal at the base of the hollowed out neck of the prostheses. This required a subsequent counterbore at the base of the neck and electron beam weld of the glass seal at this location. As a result of this design change, new glass seals with hollow feedthroughs were necessitated for the stem tip so that the platinum leads could be extracted. This revised procedure has been implemented for all the units including the ball neck unit. After electron beam welding of the feedthrough and the cap of the ball on the ball neck unit, it was subjected to hermetic testing to determine the hermeticity of the welds. Tests results indicated that the helium leak rate is less than $1.9 \times$ E-07 cc/sec.

Tests of the transmitter submodule indicated a large deviation in oscillator frequency during bench tests. The stability problem was traced to a group of four capacitors used in the oscillator resonator network. The parts substituted for original parts that are no longer available exhibit a very high temperature coefficient. Replacement capacitors have been received and submodule refurbishment has now been completed.

Fixtures to hold the multiplexor and transmitter submodules have been assembled. Accelerated life tests of these submodules are scheduled to begin after sealing of the 12 units.

A static load unit which has been instrumented with strain gauges only, welded and the final machining completed is currently undergoing static and fatigue testing on the MTS-612 servohydraulic testing machine to determine the gauge bonding durability and to establish the structural performance criteria of the implant. The remaining units are having the primary feedthroughs welded and the electronic subassemblies incorporated. They will then be returned for final machining and polishing prior to cadaver implant testing.

Due to the substantial changes which have been necessitated a change in the scope of the project has been incorporated. The use of a primary seal at the base of the neck allows us to forego the proposed leach tests since the hermeticity of the unit has been verified. Due to the redirection of effort, the expansive data recovery system originally envisioned will not be possible with current funding.

Quantitative Analysis of the Effect of Total Hip Arthroplasty on Stress and Strain in the Human Pelvis

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — New acetabular cup designs and techniques for implantation have been proposed to further improve the overall performance of the arthroplasty. However, there has been little objective experimental work done to evaluate the effects of these changes on the stresses and strains developed in the human pelvis following implantation.

The long-term objective of this ongoing investigation is to quantitatively evaluate the effects of different insertion techniques and the use of currently available acetabular prosthesis designs on the strains in the cadaver hemipelvis. It is felt that pelvic strain changes may predict the long-term success or failure of arthroplasties of the hip. Thus, our investigative methods should prove to be an aid to predicting performance or for future screening of designs and techniques.

Progress — Initial work led to the development of an automated computerized data acquisition system and customized loading fixtures. This novel instrumentation allows for the simultaneous application of prosthesis loading and simulated muscle pull to allow assessment of surgical technique and device construction of pelvic strain during the simulation of single limb stance.

To date, techniques which have been studied involve: 1) the perforation of the acetabulum with various sized pilot holes; 2) removal of various amounts of subchondral bone and cancellous bone; 3) the use of keying holes of different sizes and placement configurations; 4) the use of hand curetting to prepare the site versus the use of mechanical reaming; 5) use of spacers to insure a uniform mantle of cement; and 6) pressurization of cement using various methods versus the use of hand packing.

Future Plans — To be studied in the future are: 1) use of surface replacement prosthesis; 2) bone grafting and 3) wire mesh reinforcement or plating. Titanium metal backing with attached plastic spacers have been evaluated. Reconstructive techniques for the deficient acetabulum are to be evaluated during our next phase of research.

Design Stress Analysis of Porous Ingrowth Hip Replacements

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Sponsor: VA Rehabilitation Research and Development Service

Progress — Preliminary three-dimensional finite element studies of the normal proximal femur have been completed. We have begun 3D finite element investigation of the effects of porous ingrowth hip surface replacement and have begun development of a 3D model which includes both the femur and the pelvis.

Several publications and presentations have resulted from the completion of the two-dimensional finite element investigation of the stresses in the proximal femur and acetabulum due to implantation of a porous ingrowth hip surface replacement and acetabular cup.

C. Knee

Minimal-Gliding Knee Endoprosthesis

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Purpose — Two major problems expected to contribute to failure of artificial knee joints are loosening and wear of the prosthesis components. Both are partly generated by shear stresses that occur when mating surfaces are gliding. In an attempt to introduce an improved version of an artificial knee joint, we have proposed a model by which the opposing surfaces of the prosthesis components can be synthesized. The criterion applied is based on minimization of the gliding motion of the endoprosthesis (believed to be associated with wear) in the range of motions commonly performed by the natural knee joint.

Progress — The main assumptions of the model are: 1) area of the contact surfaces depend on the forces transmitted within the joint; 2) contact areas assume the shape of the femoral component, the deformation of which is negligible; and, 3) deflections within the joint space are mainly due to the tibial component, in view of its relatively low elastic modulus. Input data to the model include mechanics of the natural knee, namely kinematics in the types of motion commonly performed, frequency of occurrence of the various motions, and anatomical data related to geometry and architecture. To supplement the data available in the literature, kinematics of the knee joint are being studied by means of a 'Selspot' opto-electronic system.

A wear-index adapted to minimize gliding yields pairs of surfaces, one femoral and one tibial, is defined from which the most suitable pair is selected.

Design Concepts for a Porous Ingrowth, Prosthetic, Tibial Component

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The objective of this study is to develop design concepts for a porous ingrowth tibial component of a total knee prosthesis based upon a knowledge of the stress fields in the proximal tibia before and after joint arthroplasty. Anatomical specimens will be sectioned, radiographed, and photographed to document geometry, distributions of bone density, and trabecular orientations. From these sections equivalent-thickness and axisymmetric two-dimensional (2-D), as well as full three-dimensional (3-D) finite element models of the proximal tibia will be generated. Similar models with various implant components in place will also be constructed. Linear models having rigid contact at all implant/bone interfaces and non-linear, contact models capable of simulating intermittent contact/separation at any or all implant/bone interfaces will be studied. With these non-linear models, the stresses in the implants, bone, and across interfaces can be determined at initial implantation and after partial or complete ingrowth has been achieved. Parametric studies will determine the effects of assumed load magnitudes and directions, implant geometries, and implant bone material properties.

In analyzing and interpreting the results, special attention will be paid to: 1) consistency between the calculated stress fields and bone trabecular morphology; 2) initial stability of the implants under various loading conditions; 3) the types of stresses created at the porous ingrowth surfaces (compression, tension, shear); 4) the pattern of bone stress change caused by the implant; and 5) the manner in which bone may remodel in response to the stress change.

New Jersey Knee Clinical Investigation

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Purpose — This project is designed to study the efficacy of non-cemented fixation of knee endoprosthetics and to define any unique problems. The study utilizes the New Jersey design knee in a porous coated model for bone ingrowth fixation. A standardized surgical protocol is followed with patient evaluation on a prescribed periodic basis. Radiographic analysis is done as well.

Progress — To date about 30 porous coated knees have been implanted with no failures, no infections, and no deaths. The recovery period is identical to the cemented type of fixation. The range of motion and patient functional level appears to be slightly better than the older method. No new problems have been noted. Patient satisfaction seems somewhat greater. To date no evidence of loosening or failure has been noted. The conclusion is that this method of fixation is better and more durable than cement fixation with no greater risk to the patient. Infection (late) may be less as well as obviating late cement failure.

Design and Evaluation of Knee Orthoses

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Sponsor: National Institute of Handicapped Research

Purpose — The primary objective of this project is to improve orthotic treatment in the rehabilitation of the knee joint. Many knee orthosis designs do not achieve their intended goal because of mechanical or kinematic mismatches, leading to motion restriction or binding, misalignment of the orthosis on the limb, and discomfort due to skin-pressure problems. In response to the above situation, this laboratory has designed and developed an improved orthotic knee joint and complete knee orthosis. It was intended that this orthosis system be applied to total joint replacement cases, as well as the vast array of other ligament-related problems that afflict the human knee joint.

The improved orthotic joints are semi-constrained and anatomically-shaped, and were shown to have minimized the pistoning constraint normally associated with orthotic joints. Stability is added to the joints by the sequential tightening of a set of inextensible Dacron straps ("ligament" straps) crossing the joint, simulating the knee ligaments. Anterior cruciate, posterior cruciate, and collateral ligament strap configurations have been designed. Since the orthotic joints minimize the pistoning constraint, significant improvements to the orthotic interface can be realized, increasing its suspension to the lower limb. Interface

improvements, based on a four-point suspension principle, include the use of a medial femoral suspension pad and a proximal tibial suspension member, each with its associated strapping arrangement.

Progress — The design of the improved orthotic joints and orthosis was finalized during the previous reporting period. A competent and reputable manufacturer/orthotics laboratory was chosen to fabricate and market the device, along with providing education regarding its design, indications for its use, fitting, etc. A portion of our effort during this reporting period was devoted to interacting with this company, providing consultations on manufacturing, quality control, and education issues.

The remaining effort during this reporting period was spent on developing a three-dimensional finite element mathematical model of a lower limb and knee orthosis, as well as setting up an experimental system to provide a "laboratory" evaluation of knee orthoses. A series of parametric analyses were performed using the finite element model, with the purpose of looking at the effect of varying certain design features upon the orthotic interface/skin boundary. The laboratory evaluation system has been nearly complete. The evaluation will involve the use of an instrumented spatial linkage and microprocessor to measure knee motion both before/after application of an orthosis and to directly determine if the orthosis is actually performing as it should.

Future Plans — During the coming reporting period a group of suitable subjects with chronic knee laxity will be defined and evaluated, as they wear different designs of orthoses.

Interaction of Total Knee Replacement Geometry with Knee Ligaments

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Sponsor: National Institute of Handicapped Research

Purpose — Loosening of the tibial component is a major factor in the failure of total knee replacements (TKR). This project is intended to identify ligamentous constraint forces that increase interface stresses to a level that may contribute to the loosening process and ultimate failure of the TKR. The resulting information from this project will form the basis for potential implant design changes, alterations of TKR surgical procedures, guidelines for choosing existing knee implant designs when faced with various clinical situations, and recommendations for improved rehabilitation and orthotic treatment of postoperative knee implant recipients. The current specific question to be investigated is whether or not the geometry of a knee implant's tibial component should allow retention of one, both, or neither of the cruciate ligaments.

The protocol for this project is to experimentally investigate the initial post-surgical state of the knee with a TKR by using a six-degree-of-freedom instrumented spatial linkage (to measure joint motion) and buckle transducers (to measure ligament forces), in conjunction with an analytical force and finite element stress analysis, to determine ligament and joint contact forces, as well as interface stresses (potential for loosening), for various existing ligament-TKR design combination.

Progress — During this reporting period the experimental system needed to perform this project has been synthesized. Improved buckle transducers have been designed, built, and evaluated. A new knee specimen external loading apparatus has been designed and constructed. An improved instrumented spatial linkage has been built, as well as a mechanical calibration device. A microprocessor data acquisition system has been purchased and installed. Computational and sampling software has been written and tested. The testing of specimens will be carried out during the coming reporting period.

A Motion-Guiding Load-Bearing External Frame for the Knee

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The goal of this work is to design external joints for the knee which guide normal knee motion, and to incorporate them in a new leg brace design. The research plan will determine average knee motion to design external joints, to model knee mechanics with external joints of different design, and to design and evaluate a new leg brace.

Progress — Knee motion was determined using cineradiography on volunteers and using static and dynamic test rigs on specimens. Computer models were generated that displayed ligament length patterns and tibial-femoral contact joints, depending on external joint design. A computer program was written to optimally design the external joints.

External joints have been incorporated into a leg brace and are now being tested in patients with various knee problems.

It was proposed that a more effective external knee joint mechanism could be designed by taking into account the complex motion of the normal knee. Two separate studies determined the amounts of rotations and displacements which occurred as the knee flexed and extended. The normal ligament length patterns and the adverse effects of imposing abnormal motions also were determined. By using the above data and by constructing the 3-D geometry of the knee, using new sectioning techniques, a computer model of average knee mechanics was formulated. With this model, a computer-graphics program was written to design the external joints. The design is based on pins moving in slots to precisely guide the motion. The external joints have now been incorporated in an "Accuflex" knee brace. The brace is currently undergoing clinical evaluation for indications including chronic knee instability, protection after knee ligament injuries and surgery, and in prophylactic situations. It is expected that production will be expanded in the future and that there will be other applications of the external joints for the treatment of knee joint problems.

The work has made a scientific contribution at several key conferences and in journals. The new leg brace should result in improved treatment for knee instability and injury problems, and will help to stimulate improved designs from others in the field. This improvement in leg brace design should enable patients to be rehabilitated quicker and with better clinical results.

Investigation of a Simplified Internal Knee Prosthesis

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The goal was to determine whether a total knee replacement could be designed using press-fit of the components directly on to bone, or with a springy layer of velour interposed without the need for cement or porous ingrowth.

Progress — The first stage was to obtain a three-dimensional model of the average knee, including the structure and mechanical properties of the cancellous and cortical bone on to which the artificial knee would be affixed. A finite element analysis showed that press-fitting was equivalent to cementing only if a perfect fit was achieved at surgery. Experiments showed that this was not usually achieved but that a velour layer compensated for minor mismatch in fits. Experiments in sheep confirmed that a velour layer reproducibly formed a protective layer at the component-bone interface, but that a direct metal interface invoked a bone response where a natural fibrous layer formed.

Based on all of the data, a new Kinematic II Press-Fit Total Knee was designed. Special fins were added to carry the various shear and rotatory forces acting across the knee. This knee has now been used over the past 18 months on 20 patients. To obtain the best possible alignment at surgery, a new accurate instrumentation system has been developed. This system is extremely simple and compact, and is in keeping with the aims of reducing costs of the total knee procedure while maintaining high quality results.

Future Plans — Analysis of histological sections from sheep patella will be conducted to compare press-fit and compliant interfaces. Computer model and dynamic testing of generic type of press-fit total knee inserted in knees will show surgical and design variables. Clinical follow-ups of press-fit total knees that were started in patients in February 1984 will be made.

Prospective Clinical Study of the Kinematic Knee

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Sponsor: National Institute of Handicapped Research

Purpose — This is an ongoing project to follow kinematic knee patients in an attempt to identify quantitative relationships between clinical data and the eventual outcome of kinematic knee replacements and to evaluate the effectiveness of this particular prosthesis in eliminating pain and restoring and rehabilitating severely disabled individuals to normal active lives.

Progress — Data were collected from hospital and operating surgeon's files. Data included component type, patient history, as well as preoperative and postoperative physical, functional, and X-ray findings. Each case outcome received a grade using the Hospital for Special Surgery Knee Evaluation scale. Finally, the development of radiographic radiolucent lines between implant, cement, and knee was recorded.

The study has been capped at 105 cases. Many of the cases have reached five-

year follow-up, while nearly all cases have a minimum two-year follow-up. However, several cases still lack complete long-term follow-up data.

Preliminary Results—To date, almost all cases have shown a dramatic improvement in their evaluation scores. There have been no revisions. However, the results still tend to indicate an almost inevitable development and progression of radiolucent lines beneath the tibial component although their onset and severity may depend on component joint alignment, cement penetration, or several other factors. Present attempts to show these relationships with statistical multivariate analysis have been inconclusive.

Efforts of the project have turned towards quantifying the progression and size of radiolucent lines. Twenty patients were called back for both normal X-rays and X-rays taken under fluoroscopy. By the fluoro technique precise alignment of the components may be obtained, allowing assured direct viewing of the implant-cement-bone interface. Radiolucent lines were measured and graded for both types of radiographs and statistical comparisons made. While no increase in the number of lines was noted, an increase in apparent thickness was. An abstract presenting results of radiolucent lines will be submitted for presentation at the 1986 annual meeting of the Orthopaedic Research Society.

Future Plans—Efforts will center on attempts to correlate clinical radiolucent line data with interface crack propagation studies. In addition, attempts to determine the subtle relationships between procedure outcome and variables recorded will continue.

IV. Spinal Cord Injury

A. General

Treatment of Central Pain in Spinal Cord Injury: A Pilot Study

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Sponsor: National Institute of Handicapped Research

Purpose — A small but significant proportion of the spinal cord injury (SCI) population develops persistent pain severe enough to interfere with activities of daily living or to become problematic in other ways. While psychological factors are often cited as contributing to the etiology and/or maintenance of chronic SCI-related pain, systematic evaluations of psychologically-based treatment efforts have not been conducted. There is a need to conduct a preliminary investigation of these factors thereby providing a substantive, objective basis for the development of future long-term inquiries into the phenomenon.

This study assessed the effectiveness of a treatment approach for the amelioration of central pain in SCI; determined whether personality measures acquired prior to treatment are helpful/useful in predicting response to treatment.

Progress — The pain treatment protocol developed by Richard Sherman, Ph.D. to ameliorate phantom limb pain in amputations was modified for use with a SCI population. This involved the use of EMG biofeedback, relaxation training, and patient education. Pain assessment procedures used included a pain behavior rating scale, the McGill Inventory, and a subjective pain rating scale. The Minnesota Multiphasic Personality Inventory (MMPI) was administered prior to treatment. Baseline pain data were collected after which the intervention technique developed by Sherman was applied utilizing single case, multiple baseline format. Pain experience/history was re-assessed post-treatment. Results were depicted in multiple baseline, single subject designs. MMPI profiles were compared against treatment outcomes.

Preliminary Results — Five treatment protocols have been completed. A number of other protocols were initiated but not completed due to a variety of reasons (transportation difficulties, patient skepticism, medical complications, etc.) MMPI results did not strongly predict either the severity of pain complaint or treatment outcome. EMG levels (both frontalis and paraspinal) were successfully reduced with biofeedback training by several patients but without apparent impact on subjective pain data. Relaxation training was as effective or more so than biofeedback in reducing pain reports in several patients. Treatment in general seemed more effective for patients with dysesthesia than those reporting severe constant pain.

One outcome of this study preceding the treatment phase was the completion of a normative study of EMG levels in SCI patients and yoked able-bodied adults.

Dr. Sherman is pursuing this normative protocol with a Veterans Administration Hospital (VAH) SCI population. Once completed, comparisons between VAH and non-VAH SCI populations will be possible.

Retrospective Analysis of the National Spinal Cord Injury Care System Database

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Sponsor: National Institute of Handicapped Research

Purpose — Systematic and comprehensive management of acute spinal cord injury (SCI) is directed towards reducing morbidity and mortality, increasing life function capacity, and minimizing costs of care associated with this catastrophic condition. Accordingly, it is desirable to establish a mechanism to evaluate performance of the organized management system addressing desired outcomes in such a way that the impact of the system compared to other pre-system or parallel non-system activities is clear. Further, assessment of system performance over time is essential to establish patterns of behavior that then may serve as a rational basis for implementing practice, policy, or programatic change(s), if necessary.

This study is evaluating, retrospectively, the performance of the Model Regional Spinal Cord Injury Care Systems emphasizing quantifiable outcome variables.

Progress — Overall system performance is being evaluated using appropriate statistical procedures. The evaluation methodology includes, but is not restricted to: 1) the relative proportion of all new SCIs brought into and managed by federally-sponsored Model Systems in a given year [national capture]; 2) average time between injury and system admission [mean time into system]; 3) post-admission death rate [mortality]; 4) post-admission medical complication and surgical procedure rate [morbidity]; 5) level of post-discharge independence, place of post-discharge residence, vocational outcome [life function]; 6) post-injury hospitalization experience [length-of-stay and re-admission experience]; and 7) costs characterized on the basis of appropriate epidemiologic variables to facilitate comparisons between early admission and delayed admission patients.

Preliminary Results — Results of the study include information on national capture; demographics, including mean age at injury; sex; race; etiology; life function; level of lesion; extent of injury; functional assessment index; place of residence; occupational status; marital status. Information on admission trends includes: days from injury to system admission; days hospitalized in SCI system; days from injury to system discharge; cost of care; survival rates; primary cause of death; select medical complications; days rehospitalized post-discharge; benefits of early admission to an organized Spinal Cord Injury Care System.

Future Plans — In the coming year we will concentrate our activities on an epidemiologic characterization of associated injuries, operative procedures, and medical complications (with particular emphasis on pressure sores) occurring among patients in the national database.

Diagnosis and Treatment Compatible Spinal Cord Injury Patient Stabilization and Transport Devices

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Progress — The work supported by this PVA grant has resulted in the preparation of tooling and fabrication and delivery for clinical trial of a carbon-fiber/epoxy backboard and improved constant-force traction device for the inter- and intra-hospital transport of acute spinal injury patients. A test frame for a lateral head restraint with one degree of freedom of motion parallel to the traction vector was constructed, and found to be mechanically adequate but needing modification to be useful in a clinical environment. Several specimens of carbon-fiber/epoxy halo were made and laboratory tested; future designs will be similar to Gardner-Wells tongs with integral summing of constant-force traction and minimum X-ray cross-section skull fixation pins.

Contacts have been made with several organizations interested in the problems of movement and diagnosis of spinal injury patients, which may yield benefits not foreseen in the original proposal.

Pain Secondary to Gunshot Wound During the Initial Rehabilitation Process in Spinal Cord Injury Patients

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Sponsor: National Institute of Handicapped Research

Purpose — Surgical management of acute gunshot-related spinal cord injury (SCI) is somewhat controversial. There is concern that routine decompression laminectomies (in which the bullet and/or bullet fragments are removed) may aggravate the patient's prognosis rather than improve it. Removal of the bullet tends to be a standard practice irrespective of whether its presence represents a life-threatening situation. It is widely accepted that removal reduces the intensity of associated pain later in life. However, there is virtually nothing in the literature supporting this contention. By contrast, other clinicians believe laminectomy may contribute to general instability of the vertebral column in addition to being partially responsible for some reported pain. Finally, there is a clinical impression that pain occurring secondary to gunshot wound may differ in character from that occurring secondary to SCI resulting from other causes.

This study will help clinicians understand intractable pain following SCI. It also will verify or refute the efficacy and desirability of decompression laminectomy and bullet removal after SCI. Specifically, it seeks to: 1) determine whether the incidence of pain reported in GSW/SCI patients is significantly different than the incidence in patients whose SCIs result from other etiologies; 2) characterize the incidence of pain reported by GSW/SCI patients epidemiologically and demographically; 3) determine the relationship between incidence of pain in GSW/SCI patients and surgical removal of the bullet; and 4) document the incidence of pain in GSW/SCI patients with or without decompression laminectomy.

Progress — This is a two-phase, prospective study. In Phase 1, pain data are being collected on all SCI admissions (except those excluded because of overlying psychosis or senility) on a weekly basis from time of admission to first definitive

discharge. Pain behavior changes are being accessed over time. Data are being evaluated with regard to epidemiologic and demographic characteristics of the population. GSW/SCI patient data are being studied to determine absence or presence/location of the bullet or bullet fragment(s). If surgically removed before this phase, the pre-surgical location is being documented. Pain history is being documented and analyzed statistically. Eventually, all findings will be reviewed with our Department. of Neurosurgery and a Phase 2, controlled study with random assignments of patients to surgical/non-surgical management groups will be undertaken. Patient outcome will be evaluated.

Preliminary Results — Presently, we are evaluating all admissions to determine if specific patients can be relied upon to provide accurate data. We are collecting weekly pain data (pain behavior, subjective (0-10) ratings, and the McGill Pain Inventory) on GSW/SCI patients during their initial hospitalization, and at six and 12 months post-injury. As of December, 1984, 18 GSW/SCI patients have been entered into the five GSW study groups: 1) bullet in canal (n = 4); 2) bullet present elsewhere (n = 4); 3) bullet removed from canal (n = 6); 4) bullet removed from elsewhere (n = 3); and 5) bullet exited body (n = 1). We also are collecting identical data on a control group of 50 non-GSW/SCI patients matched by neurologic level and extent of lesion, and in most cases by sex.

Future Plans — Data collection will proceed through May, 1987.

Aging and Spinal Cord Injury: Research Needs Study

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Purpose — Beginning in November, 1984, the project's purpose was to report the status of research in aging and spinal cord injury. The project strategy was for a three-part approach. First, conduct a literature search into the medical, psychosocial, economic, environmental, and support services issues associated with aging in the spinal cord injured. The search would include books, scientific journals, and conference papers and/or reports. The priorities for the search were specific to aging and SCI, aging and other chronic disabilities, and finally a general search on gerontology. The second approach called for Dr. Trieschmann to conduct three small conferences of aging SCI individuals and their spouses. These conferences would provide an opportunity for individuals to share their concerns and priorities during the aging experience. The final approach was to interview select professionals in SCI who might be able to verify and/or dispute information/ trends identified during the first two approaches.

Progress — After six months, the project has become involved actively in all three approaches. As assumed in the design of the literature search, there was found to be a small amount of specific relevant research literature. It was somewhat unexpected that the amount of literature on aging and other chronic disability also was very limited. On the other hand, the general search of gerontology literature necessitated further limitations to prevent it from over-

whelming project time. Regarding the small consumer conferences, Dr. Trieschmann found that due to very real human considerations the aging SCI person and his/her spouse was not disposed positively to sharing personal concerns and priorities in a conference setting. Their eagerness was much greater in the privacy of an interview session. Dr. Trieschmann has contacted select individuals and invited them to interview regarding their experiences with the aging process. These small interviews have proven to be insightful in matters ranging from spouse survival and the reliability of the veteran's benefits for his family upon his death to confidence in the present medical profession and its apparent lack of experience in dealings with the problems of aging SCI persons. Many voiced concern that current medical interventions for the kinds of problems facing the aging population were untested with regards to the aging SCI person, making it difficult to remain confident that current accepted practices would be safe for them.

The interviews with selected professionals have been conducted by Dr. Trieschmann through contacts at conferences and/or conventions, or through initiated personal contacts around the country. These interviews have confirmed some concerns among the SCI population, and providing further introductions to individuals knowledgeable in these issues. The project is scheduled for completion in November, 1985.

Economic Consequences of Severe Disability

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Purpose — Researchers at the Bureau of Economic Research at Rutgers University are conducting a study funded by PVA's Spinal Cord Research Foundation to assess the economic consequences of spinal cord injury. New surveys of the spinal cord injured population are necessarily expensive and time consuming, so we are attempting to use existing data sources such as the 1978 Social Security Survey of Disabled and Nondisabled Adults and the Health Interview Survey to shed some light on the economic consequences of spinal cord injuries. These general surveys contain a wealth of economic information about disabled persons. We plan to compare the economic status, medical expenses, transfer payments, functional limitations, and a host of other relevant variables of spinal cord injured persons with other disabled persons or with demographically comparable nondisabled persons.

Progress — Three issues that impact on this study of the economic consequences of SCI are being intensively studied: 1) methodological problems in using secondary data sources to identify persons with specific disabling conditions; 2) potential benefits and costs of vocational rehabilitation; and 3) differences in health care use and expenses among persons with different disabling conditions.

All three aspects come together in the models designed to predict earnings and labor force participation of the severely disabled population. It is in the labor market where one observes the greatest economic consequences of spinal cord injuries and other severe disabilities. Detailed information collected in the surveys

on health status, insurance coverage, and receipt of such transfers as veterans' compensation, Social Security Disability Insurance, and Supplemental Security Income can be incorporated into the standard models of labor market behavior.

The results could be useful in pinpointing and measuring disincentive effects of benefits programs as well as evaluating the consequences of changes in program eligibility rules.

Phantom Sensations Experienced by Complete Spinal Cord Injured Veterans

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Sponsor: VA Rehabilitation Research and Development Service and U.S. Army Clinical Investigation

Purpose — Our clinical experience and initial research have led us to believe that pain which appears to come from areas below the level of normal sensation among people with spinal cord injuries is far more common and debilitating than has been supposed. This type of pain is frequently referred to in the literature as phantom body pain. It is an uncomfortable sensation that feels as though it is coming from an area of the body no longer having sensory nerve connections with the brain. The most common example is the pain experienced by amputees which they can describe in great detail as coming from a particular portion of the amputated limb. Spinal cord injured people who clearly have no normal sensations from a particular area below the level of spinal cord interruption frequently report pain from that area.

Progress — Thirty-five patients with clinical diagnoses of complete transverse spinal cord tissue destruction were interviewed about any sensations they felt below the level at which normal feelings were evident. All reported experiencing various feelings most of the time and thirty-three reported that some of those feelings were usually quite painful. Videothermographs showing differences in skin temperature of 0.1 degrees celsius were taken to evaluate blood flow patterns to a depth of 1.5 centimeters. Changes in blood flow patterns were found to correlate highly with the level at which sensations changed from normal to abnormal and to correlate virtually exactly with the locations of pain reported from supposedly desensate areas.

We propose to survey enough spinal cord interrupted veterans (5,000) to determine the actual characteristics, prevalence, and severity of pain below the level of normal sensations. The survey also will cover treatment effectiveness. This will establish if there is a major unrecognized problem not being adequately dealt with and, if so, give us a basis for understanding it. Mail response surveys will be sent to 5,000 spinal cord injured veterans identified by the Veterans Administration.

We also propose to carry out physiological evaluations of muscle tension and blood flow among at least 100 spinal cord interrupted veterans to look for correlations between phantom body pain and changes in these parameters. Multiple recordings will be done on each patient so changes with pain intensity and time can be evaluated and controlled. If we do confirm and extend these correlations, in further research we can apply modified versions of our reasonably successful phantom limb pain treatments to phantom body pain. We hope this will result in the development of good, lasting treatments for a currently difficult problem.

Spinal Cord Studies

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Use of Hyperbaric Oxygen in Patients With Spinal Cord Injuries

Forty-six patients have now been treated with hyperbaric oxygen, most receiving two treatments, each of 90 minutes duration with two hours between each treatment. We continue to use 2.5 ATA. Patients who have incomplete spinal cord lesions still appear to recover more quickly than would otherwise have been expected. Final motor and sensory recovery in these patients is still being assessed and compared with those patients who received treatment without the use of hyperbaric oxygen.

Study of Cortico/Sensory Evoked Potentials (SEP)

This project initially involved studies in 250 patients. Patients continue to be investigated on admission in order to assess the degree of spinal cord injury during the period of "spinal shock." Portable equipment is now available to facilitate studies on spinal cord function in patients within hours of injury.

Study on the Life Expectancy of Paraplegic and Quadriplegic Casualties

This study is continuing to provide information on reduction of life expectancy in paraplegic and quadriplegic casualties admitted to the specialized Spinal Units, and receiving adequate follow-up care on discharge. Results of this project are now in the final stages of analysis and are being prepared for publication.

Development of a Portable Respirator

Further developments have resulted in the supply of a suitable portable respirator for use by a high level quadriplegic patient returning to a country area to live. The "Life Pack" portable respirator widely used in North America is now being assessed for patients returning to remote areas in this country.

Supra-Pubic Drainage of The Neurogenic Bladder

The "Cystocath" has now been used for several years as a means of avoiding overdistension and infection in the neurogenic bladder. The initial analysis of 60 patients who had immediate drainage of the paralysed bladder with supra-pubic catheter drainage confirms that 77 percent of these patients have remained free of significant urinary tract infection and avoided over-distension of the bladder prior to bladder training.

Development of Low Cost Appliances

Sixty-five lightweight plastic wheelchairs have been built with improvements to meet the various needs of patients, both here in Australia and in the South Pacific areas. This research project is continuing with the development of other specialized equipment for high level quadriplegics. Environmental controls are being studied and adapted for individual patient use. The emphasis is put on using readily available materials.

Education And Prevention Program

Four researchers are involved in presenting an Education and Awareness Program in order to reduce the incidence of spinal cord injury in the community.

Over 80,000 school children have been contacted through presentations by the four members of the Resource Team. An analysis of the success of this Education Program will continue.

The Computer Training Program

A computer has been installed in the Occupational Therapy Department and patients are being trained in the use of the computer in order to widen the prospects for employment on their return to the community.

The Use of EMG Biofeedback and Functional Electrical Stimulation in Spinal Cord Injury

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Purpose — The purpose of this project is to determine the relative effectiveness of Electromyographic (EMG) Biofeedback, Functional Electrical Stimulation (FES), Occupational (OT) and Physical Therapy (PT), and specific combinations of these modalities on the restoration of function in persons with spinal cord injuries.

Progress — Eighty persons with incomplete spinal cord injuries at level C3 through C7 with resulting quadriparesis will be matched according to level of injury, muscle strength, EMG recruitment and activities of daily living, and then be randomly assigned to one of four groups: 1) EMG Biofeedback-FES; 2) EMG Biofeedback-OT, PT; 3) FES-OT, PT; and 4) OT, PT-OT, PT. Eight weeks of each treatment modality will be provided two to three times per week in sequence. Measurements of muscle strength, EMG recruitment, active and passive range of motion, and functional performance in activities of daily living will be taken prior to the start of the experiment after each treatment segment and at a six-month follow-up.

EMG recruitment will be measured by a specially designed multi-processor computer system. This unit also will provide the EMG Biofeedback on several muscle sites simultaneously according to pre-established operant conditioning procedures. Passive and active range of motion will be measured with goniometers and standard testing procedures. Muscle strength will be measured on a five-point scale using standard OT-PT procedures. Functional activities of daily living will be assessed by instruments specifically designed for this study. The OT and PT treatment will be provided by therapists with expertise in spinal cord injury according to standard treatment protocols for increasing function. FES will be provided by a computerized system according to the pre-established protocols.

Preliminary Results — The measurement instruments to be used in this study have been developed and tested, the treatment protocols have been established, and personnel, equipment, and supplies are being acquired. In addition, the possible subject population have been identified and initial screening of subjects is currently taking place.

P. L. 480 Paraplegia Project, Madras

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Sponsor: National Institute of
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Purpose — The main aim of the Paraplegia Project, Madras, is to develop simple methods of care of SCI patients in a general hospital set-up without reliance on expensive equipment. Such methods, if found to be effective and useful, have the merit of immediate transfer of appropriate technology to other parts of India and other developing nations with socio-economic conditions similar to India.

The specific objectives are to:

1) Establish within the catchment area of Madras City and adjoining districts within a radius of 200 miles, a multidisciplinary system of care providing comprehensive services to meet the wide range of needs of persons disabled by spinal cord injury. This will take place from the point of injury, requiring emergency treatment and transportation, through acute care, and early rehabilitation (including vocational and educational preparation, job placement, and long-term follow-up).

2) Demonstrate and evaluate the effectiveness of the system with regard to benefits to the spinal cord injured person and determine the cost of care for each. Specifically, it is anticipated that the system approach when compared to the non-system will result in: decreased incidence of spinal cord injury; decreased mortality; decreased morbidity; that is, less extensive spinal cord damage and fewer complications; increased function in terms of independence in activities of daily living, mobility, educational and vocational achievement; and, decreased duration and cost of acute and rehabilitation care.

3) Demonstrate and evaluate simple methods of care consistent with available resources and without emphasis on costly bed systems and equipment.

4) Facilitate education of medical and allied personnel in the management of spinal cord injury and of the public for the prevention of spinal cord injury.

5) Establish within the system a rehabilitation research environment of knowledge leading to reduction or treatment of complications arising from spinal cord injury.

6) Develop and maintain effective administration and resources to a high level of system performance.

Progress — Four hundred and ninety-nine SCI patients were treated from January, 1979 through December, 1983. Nearly 90 percent of the patients were males. Falls from heights or into wells were the commonest modes of injury (66 percent). The patients admitted within 72 hours and those admitted after that period were called System and Non-System cases, respectively. The majority of patients were treated by conservative regimen. The Madras method of acute care of flexion injuries of the spine is considered the most significant contribution of the study. The neurological status of SCI patients in this study showed statistically significant improvement when compared to several centers in other countries, with the exception of Tokushima series from Japan (where the common mode of injuries was also falls).

The incidence of pressure sores declined drastically with the two-hourly turning schedule of the Madras method. Nineteen percent of System cases and 45 percent of Non-System cases had pressure sores.

Psychosocial and vocational rehabilitation was given for all surviving patients. One hundred and fifty-two mobility aids and appliances were given free of cost to patients needing them. One hundred and forty of 393 System patients were vocationally rehabilitated. Psychiatric and psychological studies were done on 31 patients. Appropriate counselling helped these patients.

The PL 480 Paraplegia Project in Madras has proved the feasibility of acute and intermediate care of SCI patients by simple methods in a general hospital set-up of a large teaching hospital. The Madras model is worthy of replication in developing countries.

Acute Spinal Injury Patient Transportation and Support Devices

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Purpose — The goals of this project are to design, fabricate and test in laboratory and clinical settings equipment for supporting and moving acute cervical spine injury patients compatible with helicopter transportation and in-hospital computerized tomography, nuclear magnetic resonance scanning and similar diagnostic or therapeutic modalities.

Progress — Under a grant from the Paralyzed Veterans of America Spinal Cord Research Foundation, a series of six carbon fiber/epoxy foam-core backboards with multiple constant-force traction devices are to be fabricated and distributed to Santa Clara Valley Medical Center (and to other spinal treatment centers selected by Dr. Wilmot of SCVMC). Other aspects of the funded project include construction of several working models of lateral head restraints, design and fabrication of X-ray compatible carbon fiber/epoxy halos or tongs for skull fixation, and conceptual modeling of equipment including the backboard/traction device as an integral part of long-term patient maintenance. Advanced studies of methods of improving communication of patient status as the patient is transferred between treatment centers, and of provision of therapies such as hyperbaric oxygen and thyrotropin-releasing hormone (TRF) during transport are under consideration.

A technique for low-cost fabrication of carbon fiber composites has been devised. A traction device meeting the force and dimensional constraints has been developed combining the best features of two previous designs. Laboratory testing of these devices will include 4-point bending tests to determine ultimate strength of samples of the backboard composite, load-deflection test of complete backboards, including one test to failure, and force output tests of traction springs at constant extension rate. Clinical use of the devices will be monitored and data on staff acceptance and patient welfare will be analyzed and compared to historical records. Negotiations have been entered into with a potential manufacturer, using an automated reaction-injection-molding method rather than hand lay-up of the backboards. A tentative agreement has been reached with the helicopter development group at NASA-Ames Research Center to measure vibration and acceleration on an instrumented dummy on various forms of backboards during helicopter transport.

Preliminary Results — Two of the backboards and one traction device of the new design have been completed and are in use by SCVMC and Stanford University's "Life Flight" helicopter team. A third board and five traction devices are under construction. Three filament-wound halos have been made (one tested to failure) and molds are being made for carbon fiber tongs incorporating a novel fixation pin design. Hospital staff acceptance of a mock-up head restraint was less than favorable, and this design is being revised. Bending tests of backboard composite samples showed adequate flexure strength. Tests of traction devices showed hysteresis in the force output between extension and retraction; changes to correct this have been incorporated. Papers describing these results and the two-year experience with an earlier prototype at SCVMC have been submitted for presentation at 1985 RESNA and ACEMB Conferences.

Outcome Studies Pertinent to the National Model Spinal Cord Injury System

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Sponsor: National Institute of Handicapped Research

Purpose — This project encompasses three studies, two retrospective and one prospective, aimed at providing additional evidence about the effectiveness of the National Model Spinal Cord Injury System Project administered previously by RSA and currently by NIHR.

The two retrospective studies capitalize upon existence of the common database established by the national systems. One study is an attempt to demonstrate that the highly advanced system of care practiced at the Royal Perth Hospital in Australia results in better patient outcomes than obtained in the less advanced care systems in the U.S.A. The second study is concerned with documenting post-rehabilitation outcomes for quadriplegic patients who, at discharge from inpatient rehabilitation, require ventilatory assistance.

The prospective study will compare the outcomes of two groups of patients. One consists of patients whose acute and rehabilitation care was provided by the Texas/South Central Regional Spinal Cord Injury (T/SCRSCI) System. It is comprised of four acute care hospitals in the Houston-Galveston area and of The Institute for Rehabilitation and Research (TIRR) as the rehabilitation setting. The second group will consist of patients who were discharged from the same four acute care hospitals but who did not receive rehabilitation services at TIRR. Data for TIRR patients are being obtained in a companion project entitled, "Assessment, Development, and Clinical Application of Strategies to Coordinate Services for Spinal Cord Injured Clients After Discharge." Data for non-TIRR patients will be obtained during home interviews using an adapted form of the interview used in the companion project.

Progress — During the project's first year, the U.S.-Australian systems study directed by Dr. William Donovan was completed, and an article is in press in Paraplegia. In that study, one data set reflected experience with 65 consecutively admitted patients whose care during 1979 and 1980 occurred in the spinal cord unit at the Royal Perth Rehabilitation Hospital in Perth, Western Australia. A second data set pertained to 1606 U.S. patients who had been cared for in one of the regional systems during the same two years.

The results indicate that decubitus ulcers, atelectasis, pneumonia, pulmonary emboli, ulcers of the gastrointestinal tract, and heterotopic ossification all occurred more frequently in the U.S. group. The difference was particularly marked for decubitus ulcers and urinary tract infections. These outcomes demonstrate that the sooner spinal cord injured patients are referred to a center capable of meeting all their needs, the less likely it is that they will develop complications that slow rehabilitation progress.

Analyses for the study concerned with post-rehabilitation outcomes for ventilatory dependent quadriplegics are nearing completion, and the prospective study comparing outcomes for system and non-system patients is continuing.

Longitudinal Assessment of Physical Therapy Factors in the Rehabilitation Process that Affect the Quality of Life of Persons with Spinal Cord Injury

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Progress — The primary objectives of this study are to: 1) determine the importance of the patient's compliance in performing weight-shifts in a wheelchair to prevent breakdown of skin in weight-bearing areas of the body; 2) improve the criteria and procedures for selecting which spinal cord injured patients should be braced and trained to become functional ambulators; and 3) determine the incidence, characteristics, and outcome of pain complaints in patients with severe spinal cord injury.

Progress — Reductions in the original level of funding necessitated reduction in the scope of the project being undertaken. Considering the resources and expertise available, we elected to defer action on objective 1 and concentrate on objectives 2 and 3. As we complete work on objectives 2 and 3, we will redirect staff effort to pursue objective 1. Patients being studied are individuals who received severe injuries to their spinal cord resulting in paraplegia or quadriplegia.

A total of 70 patients between the ages of 20 and 58 years with paraplegia have been studied in pursuing Objective 2. A list of patient attributes and equipment and services associated with the gait training program was compiled for each patient. Follow-up evaluations six months to several years after bracing are being made to assess brace utilization. We expect the results to improve the criteria for selection of those who will remain users of braces.

A total of 135 patients between the ages of 11 and 80 years (74 with quadriplegia and 61 with paraplegia) are being studied in pursuing objective 3. Information on pain status, method of treatment, and reported success of treatment is gathered on a weekly basis until time of discharge. We expect the results to illustrate trends in the etiology and resolution of pain complaints.

Preliminary Results — Thus far we have: 1) analyzed the results of brace utilization by 70 patients who received bilateral knee-ankle-foot orthotic devices and drafted a report of the findings; 2) begun pilot studies with an orthotist to devise a simplified, modular, lightweight orthotic device for early bracing and gait training; 3) gathered and categorized data concerning the pain complaints made by 135 patients with spinal cord injury during their initial hospitalization for

comprehensive rehabilitation; 4) examined correlations between population variables, etiology of injury, level and neurological completeness of injury, and location and suspected etiology of pain complaint; 5) documented the status of each pain complaint at the time of discharge; 6) identified therapeutic procedures that patients reported as most effective in alleviating individual pain states; and 7) initiated a prospective study designed to test the relative effectiveness of specific therapeutic interventions in alleviating particular types of pain.

We plan to continue analyzing these data to look for relationships that will shed additional light on the mechanisms responsible for the state of discomfort and the mechanisms responsible for alleviation of discomfort.

Assessment, Development, and Clinical Applications of Strategies to Coordinate Services for Spinal Cord Injured Clients After Discharge

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Purpose — There are three major project objectives: 1) assess current strategies employed after discharge to achieve psychosocial adjustment and productive lives for spinal cord injured persons; 2) develop and test new strategies or refine current strategies to enhance outcomes postdischarge; and, 3) facilitate the integration of new and tested strategies into the service delivery system at The Institute for Rehabilitation and Research (TIRR) and disseminate the strategies to other appropriate sites. Methods include interviewing rehabilitation professionals and spinal cord injured clients to assess needs and resources, collaborating with service providers to develop and test improved strategies to address unmet needs, and assisting integration of the improved strategies into the service delivery system. Approximately 150 spinal cord injured persons over 14 years of age who were admitted to TIRR for comprehensive rehabilitation from 1979 to the present will be interviewed. Rehabilitation professionals from a variety of disciplines will be interviewed and/or serve as an advisory committee. The benefits expected from this project include meeting needs early to avoid compounding problems, utilizing resources efficiently by tailoring programs to meet the actual needs of clients, and improving rehabilitation outcomes by providing appropriate services.

Progress — A protocol was developed for interviewing rehabilitation professionals. Eight professionals from six rehabilitation disciplines were asked to describe the needs of SCI clients following discharge, the resources available to meet those needs, and the systems for linking the clients with the appropriate resources. Eight broad categories emerged: Health, Activities of Daily Living, Living Arrangements, Vocational, Psychosocial, Transportation, Financial, and Societal Issues and Policies. The list of needs described by the professionals was used to develop an interview protocol for use with clients to determine needs, utilization of formal and informal resources, how they found out about resources, satisfaction with resources, and special difficulties encountered in meeting their needs.

From a pool of approximately 600 eligible clients, 115 interviews have been completed. Data collection will continue throughout 1985. Preliminary analyses of the first 97 interviews indicated major differences in selected variables when subjects were grouped by race, sex, extent of injury, and time since injury. For

example, 31 per cent of the whites were employed, whereas 22 per cent of blacks and 8 per cent of hispanics were employed. Males had an average monthly income of $1156 and the average for females was $611. We are working collaboratively with the National Spinal Cord Database and the RTC project on Outcome Studies Pertinent to the National Model Spinal Cord Injury System.

Longitudinal Assessment of the Utilization of Upper Extremity Assistive Devices Prescribed for the Spinal Cord Injured Quadriplegic

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Purpose — Upper extremity assistive devices are frequently prescribed during the rehabilitation of SCI quadriplegics. However, though these devices are used daily during hospitalization, they may be discarded once the individual leaves the hospital environment. The primary objectives of this study are to: 1) identify functional categories of assistive devices prescribed for quadriplegics; 2) determine utilization of and satisfaction with those devices one year and two years following rehabilitation; and 3) determine factors responsible for discarding devices.

This is a longitudinal prospective investigation in two parts. Phase I of this study is a review of 102 charts of quadriplegics to determine functional categories and frequency of prescription of upper extremity assistive devices. Phase II employs an oral questionnaire of 75 patients to ascertain utilization of and satisfaction with devices prescribed during a first rehabilitation experience. This questionnaire is administered one and two years following discharge.

Satisfaction is determined using a Likert scale. It addresses the device characteristics of fit, cosmesis, mechanical, and functional performance. Factors that result in discarding a device include improved physical function, mechanical failure, alternative solutions, modification of living arrangements non-compliance, device outgrown or unattractive.

Progress — One hundred and two charts of quadriplegic patients were reviewed to establish the functional categories and frequency of prescription of upper extremity assistive devices. Feeding devices were prescribed to 49 percent of patients, splints and slings 87 percent, dressing 30 percent, hygiene/grooming 22 percent, and communication 20 percent. An oral questionnaire developed to determine device utilization and level of satisfaction was administered to 77 former patients one year following their first rehabilitation experience. Two hundred and sixty-two devices had been prescribed; 67 feeding, 116 splints and slings, 18 dressing, 19 hygiene and grooming, 30 communication, and 12 miscellaneous. At the end of one year, 151 devices (58 percent) were still in use (36 feeding, 75 splints/slings, 7 dressings, 8 hygiene/grooming, 17 communication, and 8 miscellaneous). On a scale of 1-5 (5 being the most satisfactory), those devices still in use were rated an average of 4.24. The most frequently cited reasons for discarding devices were improved physical function and alternative solutions found. Discarded devices represented a cost of $5400 or 35 percent of the total expenditure for all devices.

Twenty-four of the original population were queried two years post-rehabilitation. Sixty-seven percent of the devices prescribed during their first

rehabilitation experience were still in use two years later with an overall level of satisfaction of 4.14 with retained devices. The remaining 53 subjects will be queried and the data recorded.

Preliminary Results — The results of this study already have influenced some of the prescription practices within the occupational therapy department. Therapists consider less expensive short-term devices rather than ordering the most expensive models of the same item. Furthermore, the OT staff is relying more on department-owned equipment from which patients may be weaned prior to discharge. Data on specific devices are being scrutinized to establish practical guidelines for their continued prescription.

Documenting and Utilizing Programs Which Provide Community Adjustment and Independent Living Services for Persons with Spinal Cord Injury

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Purpose — The purpose of this project is to collect and maintain information about independent living and community adjustment programs that serve spinal cord injured people, to provide an effective means of communicating new ideas and experiences between individuals operating these programs, and to provide access to a dependable source of technical assistance related to these programs.

Progress — Non-experimental survey methodology is being used. The data are summarized in frequencies according to specified categories of interest, and some correlational studies are being done to determine trends in independent living program development. Data from project surveys are used to assess the types of services being provided for persons with spinal cord injury, and the source and amount of funds being utilized.

In order to facilitate use of the information which is developed, the project maintains a telephone communication network with all the extant independent living programs and approximately 150 additional individuals. Knowledge transfer strategies depend on the specific topic or set of information, but they usually involve extensive reviews of existing literature, interviews with independent living program administrators, staff members, and consumers, and supplementary reviews by additional experts both in and out of the independent living field.

Preliminary Results — The findings of this work are being disseminated in several forms. A directory listing all identified independent living programs is in its second edition. A registry profiling 164 independent programs in detail is available to spinal cord injury treatment programs, persons with spinal cord injuries, and others interested in independent living. An analysis of the data listed in the registry is in press as well as a monograph in the ILRU Occasional Paper series. The ILRU project is continuing its training, networking, and information dissemination activities in the area of independent living and maintains an ongoing effort to update its databases.

Vocational Evaluation for Quadriplegics with a High School Education or Less

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Purpose — The project objective is to develop a vocational evaluation process that will expand the vocational options for spinal cord injured persons who are quadriplegic, who have a high school education or less, and who have either a limited work record or a job history incompatible with current functional limitations.

Methodology involves: 1) identifying and documenting jobs that can be performed by the described population group; 2) conducting a comprehensive review of existing vocational assessment tools and determining relevance of tools to assess the potential of quadriplegics; 3) selecting and organizing a meaningful process; 4) incorporating the model vocational process into the Vocational Department's service delivery program; and 5) evaluating the effectiveness of the model evaluation process.

The expected outcome of this project is the establishment of a more effective and realistic vocational evaluation process that can be used to assess the job potential of quadriplegics. The project also may have implications for other disability groups with severe physical impairments.

Progress — This project is nearing completion of the developmental phase. Of 12,278 jobs that have been reviewed, 497 have been judged by the project staff to be options for quadriplegics with a high school education or less.

A total of 334 vocational assessment tools have been reviewed. Of this total, 55 commercial work samples, 18 non-commercial work samples, and 15 psychometric tests were determined by the project staff to be within physical capabilities to be performed by quadriplegics. Activities planned for the forthcoming year include: 1) identifying the occupational outlook of the jobs identified as suitable for quadriplegics; 2) selection of assessment tools applicable to measuring potential for identified job options; and 3) organization of the vocational evaluation process.

Development of Reconditioning Exercise Program for Patients with Paraplegia

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Purpose — The overall purpose of this project is to develop a testing methodology and to evaluate an exercise training program for the physical reconditioning of the patient with paraplegia. The expected outcome is the formulation of guidelines for the prescription of exercise and the documentation of the effects of physical conditioning programs for the patient with paraplegia. Male paraplegics between 18 and 50 years of age, free from disorders which contraindicate relatively high levels of exercise, and who have reached a suitable status in their rehabilitation process, will be selected for participation in the project. A minimum of five patients is to be studied in each of five categories of training modalities. Each participant will be initially administered an exercise stress test consisting of interviews, blood sample for biochemical analyses, resting ECG, physical exam, and a graded arm ergometry test using an interrupted steady-state

protocol. Expired gas will be collected during the last minute of each exercise phase. The training program modalities will consist of prescribed unsupervised exercise at home or exercises in a gamefield especially designed for wheelchair patients. Other patients will perform prescribed exercise under supervision in the laboratory or gamefield. Initially, the exercise period is for five to ten minutes increasing to 20-25 minutes with training. Training will be three days per week for eight to 12 weeks. After training, the patient will be subjected to a post-training study in which the testing of the first study will be repeated.

Progress — Methodological accomplishments this year have been the inclusion of blood lactate determinations to the biochemical studies being conducted. Monitoring of heart rate during physical exercise can now be accomplished by portable battery-powered telemetry systems.

The assessment of the cardiovascular tolerance to physical work with arm exercise has been extended to 22 untrained paraplegic males, some more than one time, and to eight healthy males tested in the same manner for obtaining comparative data. One well trained paraplegic male was tested following a self-imposed training program. Other paraplegic males have been placed on prescribed physical exercise training programs under close laboratory supervision and unsupervised training at home. One paraplegic patient has been tested in the gamefield following training. The healthy subjects were tested in the laboratory using both arm and leg exercise. Four participated in testing in the gamefield.

B. Medical Treatment

[See also pgs. 41, 42, 150, 154, 203, 204, 207, 230]

An Ultrasonic Bladder Sensor for Persons with Incontinence

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Purpose — The purpose of this project is to develop and evaluate an unobtrusive, portable device that will continuously monitor bladder volume using ultrasound. Such a device will assist persons with mental retardation who have not learned independent toileting skills to learn the association between the internal state of bladder distention and the act of engaging in a toileting routine; it also will allow persons with inadequate sensation to independently monitor their internal state.

Progress — In the first year of funding, project goals include: 1) the establishment of a comprehensive database of research and clinical reports on incontinence, of centers investigating incontinence, and of manufacturers of assistive devices for incontinence; 2) the determination of anatomical/physiological parameters for proper positioning of the bladder sensor; 3) the development of a breadboard/rack-mounted prototype of the sensor; and 4) the design of, and arrangement for, the extended behavioral research to evaluate the prototype in client service settings. At the time of writing, over 40 patients at the Medical College of Virginia were tested to determine the parameters of a bladder's internal

positioning. An extensive computerized database on incontinence articles, vendors, and research centers was established and offers free computer access to any interested party. Experimental design of the Beta field tests was developed.

Future Plans — In the remaining two years of the project, the extended Beta tests will be conducted in vocational programs of the ARC-Peninsula and in classrooms of the Dallas Independent School District. Objectives of the behavioral research are to: 1) collect information on the durability, reliability, and flexibility of the initial bladder sensor design; 2) quantify and validate the utility of the sensors in providing increased independence in toileting; 3) provide a solid base for the eventual marketing efforts of the bladder sensor; and 4) develop information on the appropriate use of the sensor and guidelines on its application for eventual users and their teachers, parents, and aides. Refinements will be made based on the results of these tests and the modified prototype will be miniaturized.

Natural History and Clinical Course of Urinary Tract Complications in Patients with Spinal Cord Dysfunction

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Sponsor: National Institute of Handicapped Research

Purpose — Appropriate clinical management of patients with neurogenic bladders resulting from spinal cord dysfunction requires 1) knowledge of the natural history or clinical course of urinary tract complications in this group and 2) data from which to determine whether urinary complications in this group are predictable from early post-injury urinary tract status and methods of early bladder drainage management.

The objectives of this study include: 1) determining the effect of method of bladder drainage management on orchitis and/or epididymitis, penoscrotal abscess, penoscrotal fistula, vesico-ureteral reflux, ureterectasis, pyelocaliectasis, calculi, and effective renal plasma flow (ERPF); 2) determining the effect of various urinary tract infecting organisms on orchitis and/or epididymitis, penoscrotal abscess, penoscrotal fistula, vesico-ureteral reflux, ureterectasis, pyelocaliectasis, calculi, and ERPF; 3) determining the effect of vesico-ureteral reflux on upper tract changes including ureterectasis, pyelocaliectasis, calculi, and ERPF; 4) determining the effect of pyelocaliectasis on cortical thickness and development of renal calculi; and 5) determining the effect of bladder calculi on bladder configuration changes, vesico-ureteral reflux, ureterectasis, pyelocaliectasis, cortical thickness, and renal calculi and the effect of renal calculi on pyelocaliectasis and cortical thickness.

Progress — Rigorous statistical analysis is being performed on a massive urologic database derived from a large series of SCI patients having a spectrum of neurologic levels and extents of injuries, and whose neurogenic bladders are/were managed in a variety of ways.

Preliminary Results — Complete studies have been performed and data recorded on 327 patients from a retrospective study group and 485 patients from a prospective group, yielding a total of 812 completed studies to date. Of 812 patients with comprehensive data, 288 (35 percent) had valid effective renal

plasma flow data one year post-injury. Neurologically incomplete paraplegics had the highest total ERPF one year post-injury (578 mls), while neurologically incomplete quadriplegics had the lowest (506 mls). In general, there was a slightly decreasing trend in total ERPF over time among all four neuro-categories. Mean ERPF of the worst kidney was highest for neurologically incomplete paraplegics one year post-injury (271 mls) and lowest for neurologically complete quadriplegics (227 mls). Once again, a slightly decreasing trend over time was observed among all four neuro-categories.

Based on the statistical analysis, the occurrence of renal stones is the most important factor leading to a diminished renal function (ERPF). Of 812 patients with adequate data, 512 (63 percent) had valid data reflecting the occurrence of renal stones during the first post-injury year. The risk of renal stones has been consistently highest among neurologically complete quadriplegics, ranging from four percent in year one to 22 percent in year eight. Interestingly, no renal stones were diagnosed among neurologically incomplete paraplegics more than three years post-injury.

Objective 4 and portions of Objective 5 have been completed. Analysis of the remaining objectives is currently underway.

Future Plans — Data collection continues. We plan to focus our attention on methods of bladder management and their association with urologic complications including orchitis and/or epididymitis, penoscrotal abscess, penoscrotal fistula, vesico-ureteral reflux, ureterectasis, pyelocaliectasis, calculi, and ERPF.

Effectiveness of Prophylactic Anti-Microbial Therapy in Patients with Neurogenic Bladder

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Purpose — The ultimate goals of an intermittent catheterization program (ICP) for patients with neurogenic bladders include removal of the indwelling catheter and maintenance of sterile urine. Recurrent urinary tract infections (UTIs) are among the most frequent causes of rehospitalization in the spinal cord injury (SCI) population. Any therapeutic modality capable of successfully assisting in maintenance of sterile urine will be an invaluable adjunct to the prevention of renal deterioration. There is a clinical need to know the relative efficacy of various drugs used to achieve and maintain sterile urine in SCI patients. This study: 1) determined the relative effectiveness of Bactrim, Macrodantin, Hiprex, NegGram, and ascorbic acid in preventing UTIs in SCI patients; and 2) determined whether treatment with any of the aforementioned drugs is superior to "no treatment" with regard to the prevention of UTI in SCI patients.

Progress — SCI patients with neurogenic bladder constituted the study population. Neurologic level and extent of lesion were documented. Upon entering the study, a urine culture, colony count, and sensitivity were obtained and appropriate antibiotic therapy initiated. After sterile urine was achieved, subjects were assigned (by ordered sequence) to one of five prophylactic treatment regimens.

Cultures, colony counts, and sensitivities were obtained weekly while the patient was hospitalized. A specific study was discontinued if and when it became necessary to replace the indwelling catheter, if the patient became reinfected, or if continued follow-up became impractical. The mean and median weeks each patient remained infection-free were calculated and the differences between each drug's ability to maintain sterile urine were measured. Changes in bacterial sensitivities to the various drugs during prophylactic administration also were determined.

Bactrim was shown to be most effective in preventing urinary tract infection in SCI patients; ascorbic acid was least effective. However, it should be noted the median infection-free period was only 15 days for Bactrim and differences between drug groups were not statistically significant. Current evidence suggests that none of the drugs tested, including Bactrim, was particularly useful in preventing urinary tract infections in SCI patients at the doses studied.

In 47 patients experiencing relapses of urinary tract infections (reinfection by the same organism that was present prior to placement on a prophylactic microbial), there were 28 infecting organisms which lost sensitivity to antibiotics to which they were originally susceptible and 16 infecting organisms which became sensitive to drugs to which they were originally resistant.

Differential Renal Function in Patients with Neurogenic Bladder

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Purpose — Renal scintigraphy has been proposed as an appropriate procedure for routine measurement of renal function in many kinds of patients, including those receiving renal transplants and those with spinal cord injuries. This test offers several advantages over intravenous pyelography, the more traditional test for long-term renal follow-up. These advantages include lower radiation exposure, less patient preparation (no dehydration or bowel evacuation), no side effects, increased patient acceptance, and quantification of renal function on a kidney-by-kidney basis. However, for this test to be acceptable it must be compared with an established standard. In this case the effective renal plasma flow (ERPF), measured by renal scintigraphy must be compared with PAH clearance, the established standard for evaluation of renal blood flow.

Progress — Seventeen male spinal cord injury patients had their ERPFs measured by I^{131} ortho-iodo-hippurate clearance during renal scintigraphy. They also had renal plasma flows measured by classic PAH clearance tests utilizing ureteral catheterization for urine collection from each individual kidney.

The correlation coefficient between total ERPF (sum of flow to both kidneys) measured by renal scintigraphy and PAH clearance was 0.83 ($P<0.01$). The correlation between single kidney ERPF, measured by renal scintigraphy, and single kidney PAH clearance was 0.79 ($P<0.01$). We conclude from this study that individual kidney and total ERPFs as determined using scintigraphic techniques are a valid estimate of renal blood flow to individual kidneys and of total blood flow.

Determinants of Renal Function Alterations During Long-Term Follow-up in Patients with Spinal Cord Dysfunction Using Radionuclide Procedures

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Purpose — The neurogenic bladder and its associated complications often result in renal disease and ultimately renal failure, a leading cause of death following spinal cord injury (SCI). Thus, the study, a long-term evaluation of the urinary tract in SCI patients is needed: 1) to verify or disprove current impressions that minimal or modest anatomic changes demonstrated by excretory urography (EXU) are not clinically significant if unaccompanied by functional alterations detected by comprehensive renal scintigraphy procedures (CRSP); 2) to establish "baseline" CRSP parameters for SCI patients; and 3) to develop a reproducible diagnostic procedure with the capability of serving as an early indicator of impending renal deterioration.

Progress — SCI patients underwent CRSPs and/or EXUs as well as other appropriate diagnostic procedures and tests such as creatinine clearance measurements. The findings were evaluated statistically. Glomerular filtration rate (GFR) was determined scintigraphically.

Over 2,300 CRSPs were performed. Expected baseline values for CRSP parameters were established for SCI patients and normal controls and the effects of age, gender, and spinal cord status determined. CRSP-IVP comparisons revealed that virtually all significant upper tract deterioration found by IVP was accompanied by renal scan abnormalities, most notably effective renal plasma flow (ERPF). Renal stones and decreases in year to year ERPF measurements and episodes of chills and fever (presumably pyelonephritis) were found to be significant predictors for the development of pyelocaliectasis. In the absence of these factors, renal function is well preserved in most SCI patients, at least for up to 10 years post-injury. Minimal IVP changes are often transient and are not considered to be clinically significant unless ERPFs are concomitantly reduced. Renal scintigraphy is currently our procedure of choice for acute and chronic evaluation of renal function.

A Practical Method of Relaxing the Neck of the Bladder and the External Sphincter of the Urethra Which Permits Voiding in Paraplegic Cats

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Purpose — It was previously reported that in paraplegic cats all the reflex responses characteristic of a flexor reflex could be demonstrated by recording motor nerve electrical activity in the pudendal nerve branch, which supplies the external urethral sphincter (EUS). We also found that in paraplegic rats single motor unit EMG activity in the external anal sphincter was similar and roughly parallel to that in the hindlimb flexor muscles. This suggested that limb muscle reflexes might be evoked to inhibit EUS overactivity (which occurs in paraplegia and many spinal injuries) if the pudendal nerve on one side had previously been severed, leaving the EUS under unilateral reflex control.

We now report that we have induced micturition in paraplegic cats by

performing limb maneuvers that evoke reflexes inhibitory to the motoneuron supplying the EUS on the innervated side.

Progress — Under ether anesthesia the spinal cords of cats of either sex wer transected at the mid-thoracic level by extra-dural ligation. A 3-5 mm segment o the right pudendal nerve was extirpated, leaving the EUS innervated only on th left. On the following day the animals were continent, and they had not voided Fluoroscopic examination revealed an overfull bladder and a closed EUS. Manua pressure on the bladder did not overcome EUS resistance to urine flow.

The following maneuvers, all inhibitory to motoneurons supplying flexo muscles in the left hindlimb, were performed: 1) left hindlimb was placed in ful flexion, stretching the extensors and reflexly causing inhibition of th motoneurons supplying the left side of the EUS; 2) right hindlimb was placed i full extension, stretching the flexors and causing crossed inhibition of th motoneurons supplying the left side of the EUS; and 3) footpad of right hindlim was pinched, evoking a crossed extension reflex of the left hindlimb and crosse inhibition of the motoneurons supplying the left side of the EUS. On fluoroscopi examination these maneuvers caused relaxation of the bladder neck, and when th bladder was squeezed, urine was seen to pass freely down the urethra.

Although this approach solves the problems caused by spasm of the externa sphincter, active contraction of the bladder (induced at the same time) would be o further advantage in obtaining complete emptying of the bladder.

Development of Analytical and Laboratory Models of the Bladder and Urinary Tract

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Sponsor: VA Hospital of Little Rock

Purpose — The main objectives of this research are: 1) design and construct device to be implanted in a dog that will apply pressure to the bladder and forc the dog to urinate (it must be possible to activate the device externally withou having any part of the device pass through the skin); and 2) develop analytical an laboratory models of the bladder, urethra, and urinary tract.

Progress — A preliminary design has been completed for a device that ca squeeze a dog's bladder hard enough to overcome the resting urethral pressure The device will allow doctors to measure the bladder pressure required to forc open the muscular valves in the urethra. The central component consists of bladder cover and inflatable inserts that can be wrapped around the bladder. A pump placed in the scrotum can be activated externally and moves fluid from reservoir placed in the belly to the inserts in the cover. The inflated inserts appl pressure to the bladder. In order to relax the bladder after voiding, one can press release valve in the pump, allowing the fluid to return to the reservoir.

A number of improvements to the current design are being considered. Nev materials and attachment methods are being investigated which will allow th device to be installed more quickly and securely. New arrangements for th inflatable inserts, which will apply more uniform pressure, are also being investigated.

Analytical and Physical Model

The objective of this part of the research has been to study the fluid mechanics which occur in the lower urinary tract of a dog; namely, the bladder, the internal sphincter, external sphincter, and the urethra. This objective is accomplished in two ways. First, a mathematical model is being constructed using the finite element method to model both the flow of urine and the reaction of the tissues to that flow. Second, a physical model is being designed and will be constructed to provide data for comparison to results from the mathematical model.

A preliminary search of the literature has shown that physical modeling has been attempted by various investigators and these physical models have been compared and analyzed. Various physical models of the bladder have been developed while very few mathematical models have been completed. Because of this, extra time and effort have been put into the development of the mathematical model, and at this time, that development has been concluded. The bladder neck and the muscles involved in micturition have been modeled using the finite element method. The finite element methods are useful in structures and fluid flow because various parameters can be inserted into the elements so as to model that particular element in a more accurate manner rather than a sweeping generalization. Furthermore, various points along the bladder wall and within the fluid flow may be checked. This is more convenient than at the boundary conditions.

The development of the program has proceeded to the point of modeling the contracted external sphincter valve by stiffening one segment of the model and observing the results. Furthermore, the model is able to produce a zero pressure difference at a specific location in the urethral so as to simulate the actual physical phenomenon which occurs in the urethra.

Bronchial Mucus Secretion in Acute Quadriplegia: A Qualitative Study

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Purpose — The major cause of sickness and death among acute quadriplegic patients is paralysis of important breathing muscles. Within one to two days of injury it is common to observe the onset of pulmonary secretions copious in amount and of a nature unlikely to be due merely to failure of clearance mechanisms. The consequences of excessive mucus in airways are increased resistance to airflow, increased work of breathing and maldistribution of each breath and the clinical consequences may be low blood oxygen levels, elevated blood carbon dioxide levels and recurrent collapse of parts of the lung. In addition, the retained secretions predispose the patients to recurrent pneumonia. Many patients have to undergo numerous therapeutic bronchoscopies at which we always find tenacious secretions in copious amounts the removal of which usually results in re-expansion of the affected regions.

The problem is perplexing in many ways. It occurs in about 20 to 25 percent of acute quadriplegic patients; non-smokers and smokers alike. It has been suggested that mucus hypersecretion occurs as a result of unopposed tone in the vagus nerve that supplies airways because, at the time of cervical spinal cord injury, the counterbalancing nerve, the sympathetic, is injured. Yet, if the patient survives,

the problem may virtually disappear after several months although the traumatic sympathectomy is permanent. The fact that it is spontaneously reversible implies that it is not due to irrevocable structural change in the airways and that it may be amenable to treatment.

Progress — We plan to study all of these patients. At present, no data are available in the literature concerning which patients may develop mucus hypersecretion. A number of factors play a role in the pathogenesis of the hypersecretion and we are maintaining a clinical database on each patient including sex, chest trauma during accident, level of injury, respiratory status before injury, smoking history, occupational history, cardiovascular disease, presence of an endotracheal tube, tracheostomy, etc.

We follow the day-to-day clinical course of all the patients and try to relate this to the respiratory system. Of particular relevance to our study is the development of lung collapse or pneumonia. These will be assessed in the usual manner by physical examination, from the chest X-ray (taken routinely), cultures of the aspirated bronchial mucus, pulmonary function tests and from measurement of blood oxygen and carbon dioxide levels, as indicated.

We anticipate in about a third of these patients (i.e. eight to ten per year) bronchial mucus will need to be aspirated on numerous occasions and will provide adequate material for all examinations as well as providing reserve for later special studies.

Our plan is to carry out a detailed analysis of the mucus produced in the lungs of quadriplegic patients in the immediate post-injury period. Our laboratory is set up to provide state-of-the-art information about the physical and chemical properties of the mucus which we obtain. The methods used are technical and complex since mucus is a complex mixture of several types of large molecules. Several important questions are being addressed. What is the nature of the mucus observed in quadriplegia? Is it always the same type? Is it amenable to treatment? As the exessive mucus wanes, does its chemical composition change? Based on our experience with other diseases, such characterizations of the mucus will help in the choice of a potential therapy and help to reduce the morbidity and mortality associated with acute quadriplegia.

Control of Respiratory Skeletal and Smooth Muscle

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Sponsor: National Institutes of Health

Purpose — Alveolar ventilation is regulated by systems that control both respiratory skeletal muscle activity and airway smooth muscle tone. The overall objective of the proposed program is to examine respiratory skeletal and smooth muscle control at the receptor, effector, and central nervous system levels.

The program consists of seven projects: 1) central regulation of respiration and circulation; 2) respiratory sensation and control of breathing; 3) neuromuscular control of breathing in human infants; 4) chemical regulation of breathing during sleep and wakefulness; 5) neuromuscular control of breathing in enzyme-induced lung disease; 6) control of airway smooth muscle and its effect on breathing; and 7) chest wall mechanics and regulation of respiratory muscle activity. These

projects will specifically investigate: 1) the interplay of neural and chemical control systems in determining respiratory skeletal muscle activity and airway smooth muscle tone in adult and infant humans and in animals; 2) the effects of higher brain centers and states of consciousness of this interaction; and 3) the capacity of respiratory control systems to compensate for changes in respiratory skeletal muscle strength, endurance and coordination produced by lung diseases.

Basic data will be obtained on the organization and operation of the respiratory controller and its interaction with other control systems. These data will be used to develop mathematical models to provide new insights into controller function. Additionally, the studies have been designed to identify mechanisms and risk factors for respiratory failure that will be useful in devising and evaluating therapeutic interventions.

Effect of Body Position on Total Lung Compliance in the Traumatic Quadriplegic

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Sponsor: National Institute of Handicapped Research

Purpose — Since extended periods of immobility can result in reduced respiratory efficiency and development of respiratory complications, the addition of respiratory muscle paralysis such as that resulting from spinal cord injury (SCI) increases the likelihood of potentially life-threatening complications or a protracted period of rehabilitation for SCI patients. For some time there has been a need for research culminating in development of a "product," in this case a "formula" that can be followed for the optimal delivery of intermittent positive pressure breathing (IPPB) therapy to enable the clinician to redirect attention to other aspects of the patient's respiratory management.

Progress — This study: 1) determined optimal procedures for measuring inspiratory volume and total respiratory compliance in quadriplegics; 2) determined whether stable end-expiratory volume can be achieved during rest in different body positions in quadriplegics; 3) measured and documented end-tidal CO2 on subjects using a proposed IPPB method to determine optimal range of inhaled pressures; 4) determined optimal IPPB flow rate for quadriplegics in a variety of body positions; and 5) measured and documented total respiratory compliance by the method of Cherniack and Brown and the end-tidal CO2 achieved via IPPB treatment on normal subjects and quadriplegics.

An instrument system capable of making required respiratory measurements was configured and validated. Pilot studies on end-tidal CO2 during IPPB treatment were conducted on control and experimental subjects. Subsequently, controlled experiments to determine total respiratory compliance were performed with subjects in the supine, seated, and 20 degree, head-down positions. Inspiratory volume measurements were repeated with subjects in positions described utilizing a spirometer. Total respiratory compliance was measured, in the specified body positions, via the method of Cherniack and Brown. End-tidal CO2 was measured, in the specified body positions, with a Bird's IPPB respirator. The "best" total respiratory compliance (via the method of Cherniack and Brown) and the ideal end-tidal CO2 during IPPB were determined. The data were analyzed using an analysis of variance for repeated measures.

Results — The difference in total lung compliance between quadriplegics and controls was of borderline statistical significance ($p = 0.095$). The effect of pressure was statistically significant ($p = 0.02$), with maximum compliance for both quadriplegics and controls occurring at four cm H20. No differences were observed among positions, and there were no significant interactions.

Controls had significantly higher inspiratory volumes than quadriplegics at all pressures and positions ($p = 0.02$). The main effects of pressure ($p = 0.21$) and position ($p = 0.16$) were not significant, possibly due to the study population's small size. However, there were two statistically significant interactions: 1) in the controls, inspiratory volume increased as pressure increased, but among quadriplegics, inspiratory volume decreased as pressure increased ($p < 0.0001$); 2) in the quadriplegics, inspiratory volume was consistently lower when patients were placed in the sitting position. In controls, inspiratory volume was generally highest when the subject was in a sitting position ($p = 0.017$).

Increasing pressures during IPPB led to a statistically significant reduction in end-tidal CO2 ($p = 0.003$). Although quadriplegics had consistently higher end-tidal CO2 values than controls in all positions and at all pressures, the differences were not statistically significant, possibly due to the small size of the study population.

High Frequency Jet Ventilation in Patients with Spinal Cord Dysfunction: A Study of Patients with Respiratory Insufficiency Secondary to Cervical Lesions

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Purpose — Patients with spinal cord dysfunction who are dependent on current mechanical methods of artificial ventilatory support cannot speak because of the need for a cuffed tracheostomy tube. Such patients have fixed ventilatory patterns that frequently do not allow for short-term adjustments in ventilation to meet transient subjective alterations in sensations of dyspnea. Thus, a need exists to develop a ventilatory technology enabling the patient to speak and use whatever intrinsic ventilatory abilities are present to meet subjective needs, while simultaneously meeting physiologic gas exchange requirements via a reliable, simple system appropriate for home use.

Progress — In this study we are: 1) determining validity and reliability of transcutaneous 02 and CO2 monitoring in quadriplegics; 2) developing and testing a transtracheal ventilation device; 3) determining specific operating characteristics of a high frequency jet ventilation (HFJV) device in quadriplegics via testing with a multi-function jet ventilator prototype; 4) finalizing design and assembly of a HFJV prototype meeting specific requirements for a spinal cord dysfunction population; 5) conducting a multi-year trial of HFJV device(s) using transtracheal appliance(s) of varying designs; and 6) conducting multi-year outpatient reliability trials.

Data collection instruments for ventilatory monitoring, state of dyspnea, work of breathing, cough effectiveness, secretion mobilization, validation of transcutaneous 02 and CO2 monitoring, atelectasis and barotrauma have been developed. Ratios of transcutaneous gas values to arterial blood values and

correlation coefficients between transcutaneous and arterial blood gas values are being developed. A transtracheal appliance is being developed and tested. Optimal ventilatory frequency and effect of pulse volume (driving pressure and duty cycle) on oxygenation and carbon dioxide elimination and optimal positive and expiratory pressure are being determined. The system design is being revised continually and new HFJV devices are being assembled (as required) and assigned for patient use. Tracheal tolerance to HFJV with the transtracheal appliance is being determined. Data on effectiveness, complications, long-term operating reliability, incidence of mechanical/electrical malfunctions, and repair requirements are being analyzed.

Preliminary Results — An improved humidifier component has been developed and tested and the gas injector component simplified. A new transtracheal injector component also has been developed.

Future Plans — Due to the low number of patients who are prospective candidates for the high frequency jet ventilator, a decision has been made to relax the inclusionary criteria in hopes of increasing the size of the study population. Thus, entry criteria have been revised so that the study population will consist of consenting adults with chronic respiratory insufficiency resulting primarily from respiratory muscle chest wall dysfunction necessitating long-term, intermittent mechanical ventilatory support.

Pharmacokinetics of Drugs in Spinal Cord Injured Persons

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Purpose — Pharmacokinetics is a discipline that deals with events taking place upon the administration of a drug or chemical to a person. The absorption of the drug into the body, distribution of the drug between various tissues, and metabolism and excretion of the drug by the liver are all part of the specific behavior characteristics of a drug in a particular individual.

From the moment of onset, medications play a major role in the management of persons with spinal cord injury. However, little is known about how the spinal cord injured person's body deals with even the simplest of pharmacologic agents (in contrast to persons with kidney or liver disorders or pediatric and geriatric populations). Following spinal cord injury, alterations have been observed in normal physiologic, metabolic, and endocrine functions. Therefore, one might expect changes in drug pharmacokinetics in individuals with spinal cord injuries. These changes can alter body levels of a drug resulting in either decreased therapeutic benefit or toxicity to the patient.

The primary aim of this investigation is to determine whether or not the pharmacokinetics of certain drugs differ in spinal cord injured patients compared to non-spinal cord injured population.

Progress — The initial investigations examine the pharmacokinetics of a class of antibiotics (the aminoglycosides) widely used in hospitalized patients with spinal cord injury. These antibiotics represent an important class of agents where the

administered dose must be carefully controlled to avoid toxicity and maximize benefits. Too high a blood level of the antibiotic can result in hearing and kidney damage. Blood levels that are too low can make an infection difficult to control. The study will examine the pharmacokinetics of each antibiotic following intravenous and intramuscular routes of administration. If these studies indicate that aminoglycoside absorption and disposition in a patient with spinal cord injury is different from that in a non-spinal cord injured patient, then recommendations as to the best way to dose the drugs will be made.

Further studies will examine the absorption, distribution, and metabolism of an anti-spastic drug, Dantrolene, in patients with spinal cord injury. Studies in able-bodied persons suggest that Dantrolene is slowly and incompletely absorbed following an oral dose. This raises the possibility that the high doses frequently prescribed for spinal cord injury may not produce the desirable therapeutic benefits. The investigation will examine the absorption and metabolism of dantrolene as a function of dose and route of administration in spinal cord injured subjects and compare the results of the oral route of administration with the data obtained in able-bodied volunteers.

The result of these studies and subsequent investigations should greatly add to the body of knowledge concerning the therapeutic use of drugs in the spinal cord injured population and result in the ability of clinicians to expand individualization of drug dosage regimen to this patient group.

Actions and Metabolism of TRH in the Spinal Cord

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Purpose — Most spinal cord injuries resulting in the permanent loss of sensory and motor functions do not involve transection of the spinal cord, but rather contusion or compression of the cord. During the first several hours after contusion or compression, impulse generation and conduction ceases, blood flow to the injured segment decreases, and the consequent ischemic hypoxia triggers extensive tissue destruction. The initial anatomic integrity of the cord observed after injury, however, suggests that recovery could be facilitated if an appropriate therapy was aimed at: 1) supporting the anatomic integrity of surviving spinal neurons; 2) enhancing blood flow within the injured spinal segments; and 3) preventing the ischemia-related tissue degeneration.

Recent neurobiological researchers have shown not only the existence of a variety of neuropeptides and their receptors in the spinal cord, but also their participation in spinal cord physiology. This has opened the possibility of using endogenous neuropeptides as drugs for augmenting nerve regeneration and the recovery from injury. For example, Thyrotropin-releasing hormone (TRH) has been shown to produce an increase in skeletal muscle tones in several species, probably by a direct action on spinal motoneurons, to activate serotoninergic receptors in lumbar spinal cord, and to potentiate neurologic recovery after spinal trauma in cats. TRH is a hypothalmic peptide that has been shown by us and others to exist both in the rodent and in the primate spinal cord. More recently, this investigator has characterized for the first time the nature of a stereospecific high-affinity receptor for TRH in the rat spinal cord.

The user of peptides such as TRH as drugs is confronted with at least two basic problems: a) their rapid metabolis by tissues and body fluids; and b) the development of receptor subsensitivity or desensitization after prolonged treatment. To make a peptide an effective drug, the investigator must devise ways to circumvent these problems.

Progress — The present research goal of Dr. Prasad's laboratory is to find means to attenuate both TRH metabolism and the development of spinal cord TRH-receptor desensitization. The maximal diminution in *in vitro* TRH metabolism is achieved by two types of experiments. First, a number of analogues of TRH are screened and those exhibiting good affinity for spinal cord TRH-receptor but resistance to metabolism by endogenous peptidases will be selected. Second, an attempt is made to decrease the *in vivo* activity of TRH-metabolizing enzymes using various pharmacologic agents. Towards attenuating the down-regulation of spinal cord TRH-receptor by TRH, potential effects of glucocorticoids, hydergine, and propylthiouracil on receptor down regulation will be evaluated. These three pharmacologic agents were selected for this study because they are known to upregulate TRH-receptors in the brain and the pituitary gland. Having achieved these goals, the researchers will attempt to study the effect of the TRH-analogues on recovery from spinal cord injury in experimental animals.

Effects of Spinal Cord Injury on Drug Metabolism

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Purpose — The pharmacokinetics of medications administered to spinal cord injured (SCI) patients have not been widely investigated. There are numerous reports regarding alterations of normal physiological, neurological, and biochemical functions in the SCI population which raise the possibility that one or more aspects of drug distribution, metabolism, and excretion may be altered in this group. The overall objective of this research is to investigate in a systematic faction a number of representative drugs commonly used at various times throughout the life of SCI patients.

Progress — Ten subjects with SCI who were to receive tobramycin either prophylactically prior to a urological procedure or to treat infection were given an explanation of the research project and gave written informed consent. All subjects had normal renal function as evidenced by creatinine clearance measurements. Eighty milligrams of tobramycin were infused intravenously by a pump over a 60-minute period. Serum samples were collected before the infusion and at 30, 60, 75, 90, 120, 150, 180, 240, 360, and 480 minutes after the start of the infusion. Serum samples were assayed for tobramycin by the EMIT method of analysis. Data were analyzed by model-independent pharmacokinetic methods.

The mean age of our subjects was 28 years (range 18 to 54), the mean weight was 65 kg (range 45.5 to 82.7), and level of injury was from T4 to C3.

Following the infusion peak, tobramycin in serum concentration averaged $3.46 +/- 0.52$ g/ml. At the end of the 8-hour dosing interval, trough levels averaged $0.26 +/-$ g/ml.

In the ten subjects studied, the mean half-life of tobramycine was 121 +/− minutes. The serum clearance (C1) averaged 155 +/− 50 ml/min or 2.45 +/− 0.69 ml/min./kg. The volume distribution at steady-state (V_{ss}) averaged 27.3 +/− 5.7 liters or .043 +/− 1/kg.

The data in the limited population studied strongly suggest that the disposition of tobramycin in persons with SCI may be quite different than in people with intact spinal cords. Both the volume distribution (V_{ss} and clearance (C1) appear to be higher in SC1. Data published for tobramycin in the intact spinal cord subject indicates average clearance values of approximately 1.87 ml/min/kg and a mean volume of distribution of 0.26 l/kg. The physiological basis for the differences are not known, but these data suggest that dosages of tobramycin in patients with SC1 requiring aminogylcoside therapy may have to be increased to provide serum concentrations to adequately cover susceptible organisms. Trough serum tobramycin concentrations were <0.30 g/ml. If one assumes that trough tobramycin serum levels should be approximately 1 g/ml, we found that in our study population the aminoglycoside concentration falls below this level at four hours post-dosing. Thus, a change in tobramycin dosage regimen in SC1 patients would be appropriate.

Factors Affecting Sodium and Water Homeostasis in Spinal Cord Injury

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Purpose — Several clinical entities are common to the spinal cord injured patient including abnormalities in salt balance, hypotension, and hyponatremia. The thrust of this research is directed towards a careful clinical assessment of factors which alter ambient levels of aldosterone and/or its precursors as well as clarifying the controlling influences of antidiuretic hormone release. It is hoped that this information will facilitate the development of new treatment strategies for hypotension and states of salt imbalance as related to both aldosterone and antidiuretic hormone.

Progress — The goal of assessing the effect of provocative stimuli on either the release/inhibition of hormonal entry into the circulation is readily accomplished with existing methodologies. This research proposal will examine a number of different tests capable of altering the release of aldosterone. These include the response of aldosterone to metoclopramide (Reglan^{R}-dopaminergic inhibitor), ACTH, angiotension II and head-up tilting. All of these tests utilize substances which are intrinsic to the body with the quantity of the test substance administered being similar to that achieved *in vivo* by the SCI patient. This testing is performed over several days with careful attention to the sodium and potassium content of the diet as well as to the body position in which the study is performed. Once the test substance has been administered, blood samples are obtained serially over two to three hours to determine the pattern of release of the particular hormone under study.

The release of antidiuretic hormone will be examined in the setting of head-up tilting, water-loading, overnight dehydration and following the administration of ethanol or hypertonic saline. All of these are proven stimulators/inhibitors of

antidiuretic hormone release and mimic aspects of antidiuretic hormone metabolism to which the SCI patient is exposed in his/her daily activities. The pattern of release of antidiuretic hormone will be determined by repetitive blood sampling. The information from this study phase is to be employed in the eventual determination of optimal fluid intake patterns for the SCI patient.

Regardless of the extent of abnormalities in antidiuretic hormone metabolism that may be discovered, they will not lead to a state of dilutional hyponatremia unless substantial fluid intake has transpired. Since hyponatremia does occur with some degree of frequency in the SCI patient, it is apparent that water intake occurs to a degree sufficient for the evolution of this process.

To this end, an as of yet unexplored area of water metabolism, thirst, will be investigated. This facet of these research studies involves characterization of the thirst response to a number of infused solutes (glucose, saline, urea). These data may substantiate the clinical observation that a number of SCI patients manifest disordered thirst regulation. This regulatory defect in thirst is such that many SCI patients routinely ingest from four to six liters of fluid daily without any significant degree of encouragement.

It is hoped that by establishing this hormonal profile in the SCI patient that a clearer understanding of both salt balance and blood pressure control may be gained. It is hoped that additional information acquired will facilitate more effective preventive strategies to avert disturbances of water metabolism.

Didronel in the Prevention of Heterotopic Ossification Following Spinal Cord Injury: Determination of an Optimal Treatment Schedule

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Purpose — Heterotopic ossification (H.O.) following spinal cord injury (SCI) or several other severe neurologic injuries and diseases can limit joint motion and exacerbate the disability, possibly impairing function and limiting ambulation or wheelchair independence to the extent the patient must remain bedfast. Recently, however, a drug, Didronel (etidronate disodium), has been shown effective in preventing H.O. when administered prophylactically after SCI.

This study seeks to: 1)determine the optimal time post-injury Didronel therapy should be initiated to achieve the maximal prophylactic effect; 2) determine the optimal duration of Didronel therapy for maximal prophylactic effect; and 3) establish dosage-administration recommendations for Didronel that are capable of yielding maximal prophylactic effect.

Progress — The study population is being made up of patients admitted to the UAB-Spinal Cord Injury Care System between 0 and 120 days post-injury, whose lesions are neurologically complete (or neurologically incomplete with residual function less than a Frankel Classification of "motor non-functional"), who are at least 16 years of age and who are not pregnant. Patients in the series are subcategorized into early and late treatment groups and further divided into three- and six-month administration groups. X-ray films of both hips are obtained one day prior to initiation of Didronel therapy, at the end of each treatment period, and at one year post-injury.

Preliminary Results — As of December 31, 1984, 121 patient/subjects had been entered into the study. Substantially more patient/subjects (n = 79) were entered into the early treatment groups (15-44 days post-injury) than patient/subjects (n = 42) into the late treatment groups (45-120 days post-injury).

The major problem has been the high dropout rate. Of 121 patient/subjects entered into the study, 65 have been dropped from the protocol, primarily for reasons beyond our control. Reasons for being dropped include, but are not restricted to, losses to follow-up, inappropriate number of drug treatment days, deaths within one year of injury, failure to acquire X-rays at the end of drug treatment, and development of clinically significant heterotopic ossification requiring continued drug treatment for at least one year.

Our preliminary results are based upon the remaining 56 patient/subjects with complete data. Three patient/subjects developed minimal heterotopic ossification while still undergoing drug treatment. Eight patient/subjects developed heterotopic ossification after drug termination. Our provisional conclusions are that early treatment is superior to late treatment, and that treatment for 180 days may be no more advantageous than treatment for 90 days.

Presently, the active study population consists of 73 patients who remain on the protocol and appear capable of and willing to be followed post-discharge. Seven patient/subjects have completed the drug treatment phase but have an annual follow-up examination pending. Ten patient/subjects are currently completing the drug treatment phase.

Future Plans — This project was originally scheduled to be completed in May, 1985. However, because of the dropout rate, we have not achieved our target of 100 patient/subjects with complete data. Therefore, we have extended this project through May, 1988 or until our target is reached, whichever comes first.

A Laboratory Test to Predict and Monitor Bone and Skin Related Complications in Spinal Cord Injured Patients

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Progress — The project starting date was August 1, 1984. Up to January 7, 1985, we have recruited 33 new patients into the project, 23 cervical spinal injuries and 10 thoracic spinal injuries. We also have done seven follow-up determinations on some of the patients from our pilot project and some of the first patients in the present project. We have eliminated four patients from the study: of the four one patient was given Na Etidronte, another one was given steroids, and another one was eventually diagnosed as incomplete and was walking with braces. This left us with 19 patients in the study.

We have started reviewing the medical charts to assess the possible temporal relationship between the appearance of clinical symptoms of bone and skin related complications and the urinary concentration of galactosyl hydroxylysine (gal Hyl) and glucosyl-galactosyl hydroxylysine (glu-gal Hyl), respectively. We have completed these chart reviews on less than half in the project according to the presence or absence of bone or skin related complications. Nevertheless, among the eight patients injured less than six months (whose charts were reviewed), there

were only two without any manifest complications. Five patients had skin breakdowns of varying severity and one patient had developed osteoarthritis of the cervical spine.

We are continuing to recruit acute spinal cord injury patients and to review their charts. In the following six months, we should be able to obtain urine samples from the patients coming back to the clinic for outpatient checkups and from patients readmitted to complete their rehabilitation program. The project is on schedule. We should have a large enough pool of acute patients and follow-up determinations by the end of the second year of this proposal, for valid statistical analysis.

Role of Antidiuretic Hormone in Cardiovascular Responses to Postural Change in Quadriplegic Subjects

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Purpose — The purpose of this study is to begin to examine the role of ADH in the orthostatic response in quadriplegics. In normal persons moving from a supine to an upright position the effect of gravity, which would otherwise cause blood to pool at one's feet and result in fainting, is counteracted by a reflex change in the cardiovascular system called the orthostatic reflex. This response is orchestrated by certain sites in the brain and the effects on the cardiovascular system are produced by a highly patterned and selective activation of the sympathetic nervous system, as mediated by nerve tracts traveling in the spinal cord.

In quadriplegic patients the spinal cord is functionally disconnected from the brain: thus, because of damage to the descending nerve tracts exerting control on the sympathetic nervous system, the orthostatic reflex cannot occur as it does in healthy individuals. When a quadriplegic is placed in a wheelchair or tilted head-up on a tilt table, his blood pressure decreases due to pooling of blood in the legs, and there is a great likelihood of fainting. However, following rehabilitation, quadriplegics can sit for hours without fainting.

Understanding the mechanism of this changed orthostatic response in quadriplegics should lead to more rapid and efficient rehabilitation therapies, enabling quadriplegics to adapt to wheelchairs in shorter periods of time. Also, therapies may be designed to deal with the persistent problem of orthostatic hypotension.

Available data indicate that the sympathetic nervous system, which usually produces this response, is not involved in the response in quadriplegics, and it has been suggested that the renin-angiotensin system takes over this function of blood pressure control. Renin, an enzyme released by the kidney, produces angiotensin which is a hormone that constricts blood vessels and thereby elevates blood pressure. Renin release is directly stimulated by a decrease in blood pressure, as well as other factors. Thus, when the normal orthostatic response is absent, as in quadriplegics, and blood pressure begins to fall when in a head-up position, the renin-angiotensin system is activated. However, it is presently unclear as to whether this is sufficient to maintain blood pressure in these subjects.

A third factor capable of elevating blood pressure and thus possibly involved in the orthostatic response in quadriplegics is antidiuretic hormone (ADH, also called vasopressin). Recent evidence shows that ADH is important in the

regulation of blood pressure, especially in the absence of cardiovascular reflexes mediated by the sympathetic nervous system. Thus, ADH may act as a backup system for the orthostatic reflex, and may take over this function in quadriplegics.

Quadriplegic subjects and healthy volunteers will be tilted head-up on a tilt table, and blood samples will be collected periodically. ADH, renin, and catecholamine levels will be measured in these samples to assess the effect of tilting on ADH, the renin-angiotensin system, and the sympathetic nervous system respectively. Blood pressure and heart rate also will be monitored, and changes in these parameters will be examined in relationship to changes in ADH, renin, and catecholamine levels. These studies should advance our understanding of the orthostatic reflex in quadriplegics and thus serve as a foundation from which to develop strategies to enhance this response in quadriplegics.

Prediction of Spared Motor Pathways and Recovery from Injury Using the Motor Evoked Potential in a Spinal Cord Impact Model

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Purpose — In the treatment of spinal cord injury the monitoring of the spinal cord's function is critical in the evaluation of treatment efforts. Surgery, involving the spinal cord or the surrounding bony structures, can give feedback to the surgeon as to whether his actions are causing harm so that he can formulate his strategies to best protect the spinal cord. There are two methods of monitoring spinal cord function. The first is the clinical examination, in which the patient follows commands from the physician. The second is an electrical test of the nervous system called the somatosensory evoked potential.

In the somatosensory evoked potential the stimulation of a nerve in the arm or leg results in electrical signals travelling up the spinal cord to the brain. These can be recorded by EEG equipment coupled with sensitive signal averaging computers to produce evoked potentials. It has been a very useful test and can be used on patients who are neither cooperative or awake, as well as those who are. However, it has been less useful than needed for good spinal cord injury care because it does not monitor the motor pathways. Instead, it monitors the dorsal columns in the posterior part of the spinal cord. Since they have a different blood supply as well as a different location and function from the motor pathways, it is not surprising that instances in both clinical and experimental literature have shown failure to predict motor weakness.

Progress — We have developed a motor evoked potential which was based initially on direct stimulation of the spinal cord when exposed during surgery. By stimulating over the area carrying the motor pathways and then recording the resulting electrical signal further along the spinal cord, we have produced a monitor of the motor system that was more accurate than the somatosensory evoked potential in determining the patient's strength after surgery.

To produce a less invasive model, we began stimulating the brain through the scalp and skull. In this method an electrode is placed on the scalp over the motor cortex and a second electrode placed in the subcranial location to direct current

down through the scalp and skull to the brain. We use the anterior hard palate. The current in the range of 30 milliamperes is applied for about one-half of a millisecond. This produces a firing of the large motor neurons in the motor cortex. Their resulting signal runs down axons in the spinal cord to the lower motor neurons, which are themselves fired, producing signals in the peripheral nerves of the arms and legs. This very weak signal can be picked up by signal averaging methods and tracked along the spinal cord and peripheral nerves. In studying it we can identify the functional status of the motor system and look for locations where the signal is blocked, weakened, or slowed.

Our investigational studies in animals have shown the signal to run primarily in the cortico-spinal pathways and in small ventral spinal cord motor tracts, including the anterior spinal tract. Other investigations have shown that these small ventral tracts are critical in both primates and cats for the recovery of basic walking function after injury. In injury studies with acute animals, we have found that the motor evoked potential is considerably more sensitive to injury than the somatosensory potential even though the injury occurs over the dorsal columns that carry the somatosensory potential.

We are beginning to study the effects of spinal cord injury in chronic animals with the specific purpose of identifying those parts of the motor evoked potential which run in the small ventral motor pathways and that are primarily responsible for recovery of ambulation after injury. We are replacing a recording electrode directly on the ventral spinal cord and identifying those components which are strongest there. We also are lesioning studies and looking for those components left in the ventral cord and then identifying them with a various statistical analysis and signal identification methods. We will then correlate those signal components that are in the ventral spinal cord with the animal's recovery function. We hope to find an index in the motor evoked potential that we can use to determine the status of a patient's spinal cord vis-a-vis walking. The index can be used to protect the spinal cord during surgery and to evaluate patients who arrive in the emergency room newly injured. It also can guide treatments used in helping spinal cord injured patients. In the laboratory it should help to best target the treatment toward those functions of the spinal cord that will result in ambulation.

Evaluation and Rehabilitation of Reproductive Function in Paraplegia

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Purpose — The overall goal of this research project is to develop and implement technology that will be useful in assisting the sexual rehabilitation of paraplegic patients as they strive to restore their normal functioning in society. Two specific objectives were established, one directed primarily toward instrumentation (electrostimulation and catheter modification), the other toward clinical utilization of this instrumentation and related clinical aspects of semen evaluation.

Progress — During the first six months of this research, eight patients were identified as possible project candidates. Their level of injury is between T4 and T12-L1. All were evaluated once using RPE, with accompanying assessment of the quality of semen obtained. Three subjects were selected for repeat RPE

procedures at three-week intervals. It is planned during the second half of the study period to increase the number of subjects to ten, with a greater percentage of these studied on a repeat basis.

Several specific topics are being addressed during this project, with answers at present remaining tentative pending further work. One formal investigative week with both Georgia-based (Martin, Warner) and Palo Alto-based (Perkash) workers took place, in December, with the three remaining week-long sessions planned for March, June, and July, 1985.

One topic involves final integration and miniaturization of the electrostimulation unit, with dial placement and inclusion of fail-safe current limiting devices designed for "user-friendly" operation. This has been done, and we have taught several medical personnel the details of how to utilize the equipment. Under the supervision of Dr. Perkash, they have gained experience in use of the equipment in carrying out the more than two-dozen stimulation sessions performed thus far. This personal interaction has improved the unit's ease of operation and led to improved protocols for semen collection. Continued experience will doubtless produce additional suggestions for an optimum stimulus protocol.

A second topic involves catheter-modification and fitting to ensure optimum capability for antegrade semen flow. Typically, we are finding that a #18 Foley 3-way catheter with balloon inflated between 20 and 30 cc is adequate, if carefully positioned, to prevent retrograde flow, thus allowing antegrade flow and collection. To this extent, we are finding that patients having had extensive surgical incision of the bladder neck (performed to improve voiding) typically do not permit as tight a seal of the Foley balloon catheter against the bladder floor, allowing retrograde semen flow during RPE. Thus, a suggestion may be to use care in such bladder neck surgery to ensure maximum improvement in voiding with minimum surgical alteration of the associated musculature. Otherwise, in such patients who desire collection and evaluation of their semen, the problems of dilution and acidification by bladder urine will be a confounding issue in evaluating their fertility status.

A third topic involves the effectiveness of repeat RPE on semen quality (sperm numbers, sperm motility, sperm morphology). While we find that semen collected by antegrade flow has better motility than that collected by retrograde flow into the bladder (morphology in both is similar), it appears that three-week intervals for repeat electrostimulation may be too frequent to permit replenishment of sperm stores. More data are required for confirmation of this. Results of testicular biopsy indicate a frequent occurrence (~50 percent) of mild testicular atrophy, which probably decreases the total number of sperm produced by the testis per unit time.

An additional topic involves the aggressive management of urinary tract infections in all patients studied, with a view toward minimizing possible deleterious effects of such infections on sperm motility. Typically, motility in collected semen is very low (<20 percent), and this poses a problem in the potential use of this semen for artificial insemination. It is well known that bacterial infection, as well as certain drugs used to minimize infection (such as mandelamine), are toxic to sperm survival. Thus, optimization of the health of the urinary tract will make it a less hostile environment for the temporary transit of sperm as they proceed from *vas deferens* through urethra upon ejaculation or emission.

A related topic involves the provision of an optimal environment for sperm survival. To enhance the survival rate of sperm directed into the bladder by retrograde flow, we are using several approaches: 1) flushing the bladder with a buffered solution prior to each RPE procedure; 2) leaving a very minimum residual volume of such buffered solution in the bladder prior to RPE to minimize dilution and ensure acceptable pH maintenance; and 3) immediate transfer of retrieved sperm to protein-containing buffered media similar to those used for *in vitro* fertilization.

Continued patient studies during the second half of this funded year should provide the additional experience and data required to improve the ease of semen collection using RPE and improve the motility of sperm obtained.

Diglycerides and Phosphatidic Acid in Peripheral Nerve and Spinal Cord During Wallerian Degeneration

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Purpose — The term Wallerian degeneration is applied to the changes that occur after spinal cord injury or lesions of the brain. The segment of a nerve fiber that lies distal to the injury is subject to the degenerative process. In warm-blooded animals and man, Wallerian degeneration of a peripheral nerve is complete in about 50 days. In the spinal cord the process is relatively slow, requiring 200 to 300 days for completion. Wallerian degeneration in a peripheral nerve is reversible. When allowed to regenerate, a nerve will restore motion and sensation to a powerless limb. In contrast to this regenerative potential in the peripheral nervous system, functional recovery after spinal cord injury is sparse or absent. The reason for this difference has not been established.

The goal of research in Wallerian degeneration of nerve and spinal cord is the discovery of the molecular events that lead to degeneration. Hopefully, recognition will permit us to prevent or retard the degenerative process. With the limited regenerative potential of the spinal cord, prevention of Wallerian degeneration after the injury would appear an attainable goal. The induction of actual spinal cord regeneration may continue to elude us.

Wallerian degeneration is associated with biochemical changes in the degenerating nerve tissue. Many of these changes are already well characterized. Since the fatty envelope of nerve fibers, the myelin sheath, proceeds to total destruction during Wallerian degeneration, myelin lipids have been studied in greatest detail.

Even though no trace of the specific lipids of the myelin sheath may be found in a totally degenerated nerve, sprouting of new nerve fibers will result in reassembly of the myelin sheath and restoration of a near normal concentration of fatty substances. As may be predicted, such biochemical healing does not occur in the injured spinal cord.

Progress — In our laboratory, a specific aspect of lipid metabolism is being studied. It is the conversion of neutral lipids to phospholipids. Neutral lipids are molecules of relatively simple structure and contain glycerol (glycerin) and one, two, or three fatty acids. Among these lipids, the diglycerides containing glycerol

and two fatty acids are thought to be the most important because they are linked to the synthesis of phospholipids. Phospholipids are rather more complex than neutral lipids because they contain glycerol, fatty acids, phosphorus, and a base such as choline or ethanolamine, or the amino acid serine.

The exchange between diglycerids and phospholipids occurs by the sequence of enzymatic reactions. Diglyceride can go on to phosphatidylcholine (reaction 1) or return to phosphatidic acid (reaction 2). Reaction 2 counteracts reaction 1, perhaps providing an important balance between the tissue levels of diglyceride and phosphatidic acid. In Wallerian degeneration of the peripheral and central nervous systems, reaction 1 is accelerated, and more phosphatidylcholine is biosynthesized. However, the process is out of control and does not lead to proper assembly of the myelin sheath. The velocity of reaction 2 during Wallerian degeneration has not been studied. The enzyme that catalyzes reaction 2 (diglyceride kinase) is present in central nervous tissue but has not been examined in the peripheral nerve. It is proposed that this cycle of reactions is disturbed during nerve and spinal cord degeneration because reaction 1 is accelerated and reaction 2 slowed or absent. If the cyclical exchange between phosphatidic acid and diglyceride can be stabilized immediately after nerve or spinal cord injury, perhaps by a drug, the destructive process of Wallerian degeneration may be brought under control and chances for recovery may be enhanced.

Collagen Dysfunction in Quadriplegia

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Purpose — This study seeks to elucidate the ways in which collagen metabolism is altered in spinal cord injury (SCI): what are the consequences of such alteration and what causes that alteration?

Project I: A method has been developed to measure hydroxylysine glycosides in an automated amino acid analyzer to establish the fact that increased concentration of a specific glycoside is an indication of the tissue origin of the collagen being degraded. It is hoped that physicians will be able to use this information to decide what preventive measures are of greatest importance for the individual patient and thus reduce the number of complications following SCI.

Project II: Density of adrenergic receptors in the insensitive skin of SCI patients is being measured by radioligand binding assays. The objective is to show that altered sympathetic responses lead to altered nutritional status of skin thus increasing its susceptibility to pressure damage.

Project III: The activity of the enzyme lysyl hydroxylase and the concentration of some amino acids characteristic of collagen are being measured in skin biopsies from above and below the injury in SCI patients. The objective is to show that SCI leads to abnormal enzyme activity which in turn leads to defective collagen biosynthesis and decreased tensile strength of the skin. If the specific defects in the collagen metabolism of SCI can be identified, they may be amenable to pharmacological intervention.

Progress — Project I: The data show that urinary excretion of both hydroxylysine glycosides is elevated immediately after the injury, reaches a peak between three

and six months after injury and returns to normal values about a year after injury. Patients with skin-related complications show a rise in glucosylgalactosyl hydroxylysine about one month prior to clinical manifestations. The relationship between urinary excretion of galactosyl hydroxylysine and bone-related complications is not as well documented yet.

Project II: Alpha adrenergic receptors show a trend towards a decrease in density with increasing time since injury. We hope to obtain enough data to achieve statistically significant results.

Project III: The lysyl hydroxylase activity assay has been tested, the effects of varying the concentrations of the several cofactors have been studied, and work on patient skin biopsies has begun.

Upon completion of these three projects, a clearer picture of the relationship of neurological deficit to somatic structural abnormalities in SCI should emerge.

Incidence and Clinical Significance of Impaired Brain Function in Spinal Cord Injury: A Continuing Preliminary Study

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Sponsor: National Institute of Handicapped Research

Purpose — Incidence statistics on concomitant brain impairment in spinal cord injury (SCI) patients are lacking. Such data are needed both in the individual case and in the aggregate so adequate planning and service offerings can be provided to patients who suffer this significant, associated injury.

This study is: 1) identifying, validating, and utilizing a battery of neuropsychological tests to diagnose impaired brain function in a series of recently injured SCI patients; 2) estimating the incidence of impaired brain function in recently injured SCI patients; and 3) determining whether neuropsychological assessment data correlate with demographic, epidemiologic, and medical data from the same series of SCI patients.

Progress — A neuropsychological test battery has been identified, evaluated for appropriateness/applicability and validity, and subsequently administered to newly admitted SCI patients. Medical, epidemiologic, and demographic data on all patients in the series are being reviewed retrospectively. All data, including neuropsychological test results, are being evaluated quantitatively and qualitatively. At the end of the data collection phase, summary data sheets will be presented to a panel of neuropsychologist judges who will not know the neurologic condition of the patients. Based upon their review of patient-specific data, they will attempt to diagnose probable brain pathology. The incidence of concomitant brain and spinal cord injury will be estimated and a determination made regarding predictive ability of neurological and descriptive measures. All data will be analyzed in an attempt to identify significant, meaningful correlations.

Preliminary Results — As of December, 1984, 99 patients completed initial test batteries and 25 of those completed repeat batteries. We are excluding patients who are psychotic, schizophrenic, those who have known premorbid organic brain impairments, and/or children under 16 years of age. We are performing medical record audits to acquire each patient's demographic data and to establish clinical

evidence of brain injury. A provisional inspection of our data suggests more impairment across a wider variety of cognitive tasks for a larger percentage of patients than originally anticipated.

An incidental but important by-product of this project has been the delineation of a comprehensive neuropsychological test battery suitable for use in a rehabilitation setting. No tests in this battery require hand function to complete; hence the battery can be used equally well by quadriplegic and paraplegic patients.

Incidence, Characteristics, and Clinical Significance of Anemia in Patients with Spinal Cord Dysfunction

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Purpose — Anemia commonly develops within the first six months following spinal cord injury (SCI), even in the absence of detectable blood loss. Some clinicians order blood transfusions if the hemoglobin falls below 10-12 Gm percent. However, prevention is more desirable than treatment. Whether anemia is due to stress, inadequate nutrition, blood loss, depressed red blood cell (RBC) production, or increased RBC destruction has not been determined. Anemia may be an important factor in the development of secondary complications. It also may delay or prolong the rehabilitation program. Thus, finding the cause of anemia in this population is a requisite to its prevention.

This study will: 1) determine those epidemiologic and/or demographic variables that affect the duration and/or severity of anemia; 2) determine the natural history of changes in the hematologic profile of SCI patients; 3) establish the natural history of RBC kinetics after SCI; and 4) determine whether alterations in nutritional profile are associated with the incidence, duration, and/or severity of post-injury anemia.

Progress — The study population is being made up of a series of neurologically complete quadriplegics who did not receive blood transfusions following their SCI. Demographic characteristics and the hematologic correlates of the population are being documented as are basic hematologic profiles. Ferrokinetic studies also are being performed. Nutritional profiles and their hematologic correlates are being established. All data will be analyzed utilizing appropriate statistical techniques.

Preliminary Results — The project was initiated on June 1, 1984. As of December, 1984, six patients had been entered into the study. All patients were males between the ages of 19 and 26 whose neurologic levels of lesion were between C4 and C7. Erythropoietin quantitative assays were performed by the Bio-Science Laboratory in Van Nuys, California.

All six patients were evaluated at six weeks post-injury. They had erythropoietin values in the low normal range (4-14 milli-immunochemical units erythropoietin/ml serum). The normal reference values are 7-36 units/ml. Only two patients agreed to participate in the plasma volume and red cell mass studies using I-125 and Cr-51. These patients had a slightly lower red cell mass than normal but had higher plasma volumes. Total blood volume was increased in one patient and normal in the other. Total body hematocrit was also low.

Future Plans — Computer entry and preliminary analysis of data will begin in the next grant year. Interestingly, it appears that despite normal peripheral red cell, hematocrit and hemoglobin counts, the serum erythropoietin level is low during the acute stage of spinal cord injury. Shrinkage in red cell mass is also possible during this time period. We will explore these preliminary findings in considerable detail during the remaining year.

The Relationship of Nutritional Status and the Occurrence of Secondary Complications in Spinal Cord Injury Patients

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Purpose — Nutritional requirements of the spinal cord injury (SCI) population are almost entirely a matter of speculation. There are many unanswered questions concerning protein requirements, lipid mobilization, and vitamin and mineral requirements.

This study seeks to: 1) determine the frequency of nutritional deficits in recently injured (viz. acute) SCI patients; 2) document secondary medical complications and examine the association between them and low or deficient nutritional parameters; 3) assess muscle mass, strength, and endurance as indicators of motor function, examining the association between these parameters and low or deficient nutritional parameters; 4) assess T and B lymphocyte numbers, cutaneous hypersensitivity, neutrophil bactericidal activity, and production of salivary IgA as indicators of immunologic function, examining the association between decreased immunologic function and low or deficient nutritional parameters; and 5) assess depression, self-concept, and anxiety as indicators of psychological functioning, examining the relationship between psychologic parameters and low or deficient nutritional parameters.

Progress — A series of 60 SCI patients with neurologically complete lesions, sensory sparing only, or non-functional motor capabilities who are between 15 and 60 years of age, without multiple fractures and without concomitant head injury is being studied throughout the course of hospitalization in the rehabilitation setting. Eventually, the series will include 30 patients with cervical injuries, 20 with lesions between T-1 and T-10, and ten with lesions below the tenth thoracic segment. A wide spectrum of nutritional variables is being measured at regular intervals. Nutritional deficiencies and secondary medical complications developing after admission are being documented and analyzed statistically. Muscle mass and work capacity are being determined and analyzed. Immune fractions are being determined at regular intervals after admission. Also, psychological evaluations are being performed at regular intervals after admission. Ultimately, all data will be analyzed and compared for the possible identification of association(s) between physiologic, psychologic, and nutritional parameters.

Preliminary Results — As of mid-December, 1984, data have been collected on 47 subjects. Twenty had cervical injuries, 14 had thoracic injuries at or above T-10, and 13 had injuries below the tenth thoracic segment.

Preliminary findings indicate that caloric intake was frequently less than 1000 calories/day for prolonged periods. Other values found frequently to be low include Vitamin A, carotene, folate, ascorbate, retinol-binding protein, transferrin, and albumin.

Allergy to mumps antigen, as reflected in delayed cutaneous hypersensitivity (DCH), was present in 87 percent of the patients, compared to 30 percent of healthy controls. Patients with low maximal inspiratory pressure (MIP) tended to have more nutrient deficiencies than those with normal MIP, and those with low maximal expiratory pressure (MEP) tended to have more nutrient deficiencies than patients with normal MEP.

Our early impressions are that nutrient deficiencies are common in the acute phase of SCI and may be associated with depressed immune response and muscle function.

Spinal Cord Injury Model

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Sponsor: National Institutes of Health

Progress — Based on our previous work in the laboratory, and that of other laboratories, we have selected two methods of injury for detailed analysis with respect to reproducibility and ability to grade the magnitude of lesion behaviorally, electrophysiologically, and morphologically. Having identified the mode of injury which best meets these criteria, this injury model will then be used for an evaluation of the effectiveness of six different treatment modalities. In order to characterize the lesion and its evolution, both longitudinal and serial observations will be made. In addition, an evaluation will be made of the relationship of treatment to intensity of injury.

Radiography and Radioisotopic Angiography of Spinal Cord

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Sponsor: National Institutes of Health

Purpose — Selective arteriography (radiographic) of the spinal cord is a diagnostic technique that has proven to be very informative in cases of arteriovenous malformation, tumor, obstructive vascular disease, trauma, and postradiation damage of the spinal cord.

Radioisotope angiography of the spinal cord offers distinct advantages as a screening method, and in certain types of intraspinal pathology may give information not available by any other diagnostic test.

Progress — Preliminary experience with new techniques, dynamic computed tomography (DCT), digital subtraction angiography (DSA), position emission tomography (PET), using 18F-2-deoxyglucose, and nuclear magnetic resonance imaging (MRI) of the spine indicates that these methods may be useful screening and follow-up procedures in the evaluation of certain vascular lesions and tumors of the spinal cord.

Reconstruction of One Level Cervical Spinal Instability (Dog)

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Sponsor: National Institutes of Health

Purpose — Rehabilitation from acute quadriplegia is frequently complicated by coexistent cervical spinal instability, in many cases secondary to ligamentous damage. Without surgery such injuries require bracing for three to six months often with the cumbersome halo-vest. Not only does this impede physical rehabilitation but even after its prolonged use, chronic spinal instability may still result. A variety of surgical procedures exist for reconstruction of the ligamentously unstable cervical spine. Few have a logical basis in preliminary research, but instead represent an individual's personal clinical experience and when attempted by others often have an unacceptable incidence of complication.

The purpose of this project is to develop a canine cervical ligamentous instability model.

Progress — Acute instability will be produced in a single spinal motion segment. Different general reconstructions will be applied to the model. The progression of instability in the model and the way in which the reconstructions alter it will be objectively studied by:

1) Serial Radiographs

2) Overload and, in some cases fatigue, flexion and extension mechanical testing using a Materials Test System—810 Unit to generate the following mechanical parameters:

a) Construct Shear and Angular stiffness, ultimate strength and energy absorption to failure.

b) Total Shear and Angulation to failure.

c) Number of cycles to failure for Constructs tested in fatigue.

d) Changing Construct stiffness as a function of number of cycles for Constructs tested in fatigue.

The above data will be statistically analyzed.

3) Histological slides of the interface between the reconstruction materials and the original spinal elements.

The above studies will be obtained (from different experimental animals) at monthly intervals postoperatively up to three months. A stability continuum for the different reconstructions will thus be created from which their strengths, weaknesses, and specific indications will be defined in a laboratory setting.

Standardized Reproducible Spinal Cord Injury Model (Mammals)

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Sponsor: National Institutes of Health

Purpose — This project will develop, test, and validate a standardized, reproducible spinal cord injury model in animals that is characterized in terms of the evolution of behavioral (functional), electrophysiological, and morphological changes arising as a result of the lesion with the primary intent of testing new therapeutic modalities for the treatment of spinal cord injury. The study is intended to demonstrate that such a model can be used for testing of new therapeutic approaches by utilizing it for evaluating medical therapies reputed to be useful in the treatment of spinal cord injury.

In the first phase of the project, we propose to determine the optimal impact conditions to establish three levels of injury (corresponding to 10 percent, 50 percent, and 90 percent residual functional deficit) using a weight-dropping device (open impact injury) in the rat.

Spinal Somesthetic Pathways (Human, Monkeys)

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Sponsor: National Institutes of Health

Purpose — The proposed studies have two major goals: 1) to improve neurological diagnosis of spinal cord injury by defining the sensory capacities that depend critically upon transmission along three major ascending pathways (in the ipsilateral dorsal column, the ipsilateral lateral column, and the contralateral ventral quadrant); and 2) to improve understanding of the participation of spinal cord circuitries in the control of elimination of pain. This is a multidisciplinary approach within the neurosciences, involving highly quantitative evaluation of sensory thresholds and motor reactions to precisely controlled somatosensory stimuli.

A variety of correlations will be made between anatomical manipulations (and measurements) and the occurrence of functional deficits. Careful attention will be directed to the capacity for recovery of function following spinal lesions. Pharmacological compounds will be introduced directly on the spinal cord to determine the importance of different descending spinal pathways and transmitter systems for inhibition of pain. Clearly defining the roles of serotonin, noradrenalin, and opiates on sensory coding and motor output at spinal levels is fundamental to understanding neural mechanisms of pain control, which should lead to new methods of pain therapy.

The proposed studies will be conducted with monkeys, because the pain conduction systems are quite similar among primates and very different between primates and other mammals. The pain stimuli are brief, non-injurious, and easily tolerated by monkeys and humans. Other stimuli will involve tactile and/or proprioceptive receptors and will test the most acuitive somatosensory functions involved in active touch or grasp of objects in the environment. Sensations of texture or resistance to pressure by the hands are crucial to the advanced manipulative skills of primates, and the proposed studies will delineate the spinal pathways involved in these functions.

National Acute Spinal Cord Injury Study (Human)

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Sponsor: National Institutes of Health

Purpose — The pharmacologic management of acute spinal cord injury in humans remains equivocal despite decades of animal clinical investigation. The National Acute Spinal Cord Injury Study (NASCIS) was established in 1977 to evaluate new treatment modalities using a multi-center randomized clinical trial (RCT) methodology. The first RCT (NASCIS I) was successfully completed in 1983.

Recent animal data suggest that high doses of methylprednisolone (30 mg/k) and naloxone (5 mg/k) may be efficacious in improving neurological recovery

after acute spinal cord injury. It is proposed to compare these drugs against placebo in a double blind RCT at 12 medical centers. The study protocols will be modified after existing ones already developed by the study group. Eligible spinal cord injury patients will be randomized to one of three treatment arms within 18 hours of injury. Standardized neurologic exams will be given on admission, 24, 48, and 72 hours, and six weeks, six months and one year after injury. Improvement in motor function, pinprick, light touch, and deep pressure sensation are the major study outcome measures. Morbidity and mortality, especially as they relate to drug treatment, will be monitored throughout the trial and studied in detail. A total of 480 patients will be randomized. Potential confounding and effect modifying factors will be examined and controlled using log linear models and logistic regression analyses.

The National Acute Spinal Cord Injury Study is one of the most detailed, standardized, and complete data sets of the management of acute spinal cord injury available. It also will be used, therefore, to test hypotheses concerning the potential advantages of surgical and other management procedures in improving neurological outcomes.

Spinal Cord Injury Research Center

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Sponsor: National Institutes of Health

Purpose — Spinal cord injury and its eventual outcome is a product of the cellular and molecular mechanisms of degeneration, growth, and regeneration. These processes may be best understood by a combination of studies that examine the acute and chronic mechanisms of degenerative phenomena. In addition, since the capacity to regenerate spinal neurons is limited in the adult spinal cord, an attempt to examine regenerative phenomena during development, when such phenomena are enhanced, is an important part of the proposed research. The specific aspects of these phenomena to be explored include an examination of: 1) the biochemical pathophysiology of degeneration; and 2) the physiology, biochemistry, and anatomical characterization of reorganization of nervous tissue subsequent to nerve trauma.

The further development and evaluation of a new injury device is an important step toward the control of injury as an independent variable. Alterations in lipids, membrane integrity and recovery, and the ability to induce changes in the metabolic (P02) or ion ($Ca++$) microenvironment will be studied to assess the effects of ischemia or impact injury to the spinal cord. Interventions into this pathological process also will be attempted with naloxone to improve tissue oxygenation and spinal hypocalcemia. The degree to which such interventions are successful also will be assessed chronically by behavioral or morphometric analysis.

Mechanisms of axolemmal synthesis are to be studied by assessing ganglioside contributions to peripheral nerve trauma. Reorganization and regenerative phenomena will be assessed in the cat and developing frog, respectively, using HRP histochemistry, intracellular neurophysiological techniques, and electron microscopy. The role of nerves in the regenerative plasticity involved in limb regeneration is also to be assessed. Only by studying acute alterations in spinal

pathophysiology and attempting to reverse them chronically can we begin to effect changes in the capacity of the central nervous system to use the inherent mechanisms of regeneration that it had, but may have lost, during development.

Clinical Research Center for Acute Spinal Cord Injuries

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Sponsor: National Institutes of Health

Purpose — The proposal for the continuation of the Clinical Research Center for Acute Spinal Cord Injuries at New York University will examine several interrelated hypotheses concerning the pathogenesis and treatment of spinal cord injury (SCI) at both the laboratory and clinical level. The major hypothesis to be tested is that the irreversible lesion resulting from injury to the spinal cord is neither immediate nor complete, and that appropriate therapy can be designed and instituted to ameliorate the multiple pathogenic mechanisms initiated by the trauma. Individual projects will look at innovative treatment regimens in experimental and clinical SCI. Information concerning the pathogenesis of SCI has been provided by the component projects of this proposal. We present three principal theories concerning the mechanisms by which trauma to the spinal cord may lead to irreversible damage.

The major emphasis of this proposal will be to test each of these hypotheses by themselves and for correlations that may suggest a common pathogenesis underlying more than one of them. The first concerns the role of endogenous opiate peptides in the damage to the spinal cord and the ability of the opiate antagonist, naloxone, to improve neurological recovery after SCI. The second deals with the causes of ischemia to the spinal cord, the effects of ischemia on the spinal cord, and methods available to prevent a decrease in spinal cord blood flow. The third hypothesis is that SCI initiates a series of pathologic free radical reactions that produce damage to critical biomembranes in the spinal cord. These pathologic reactions are amenable to control by specific pharmacologic methods. The concept of the development of an irreversible spinal cord lesion at some time after trauma carries with it the inherent view that the initial events are not sufficient by themselves to cause devitalization of tissue but require the progressive development of interrelated pathologic responses. It is to these latter events that therapy will be directed.

A Center for Acute Spinal Cord Injury

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Sponsor: National Institutes of Health

Progress — This program is a multidisciplinary approach to the problems of spinal cord injury (SCI). Included are: an epidemiological study of spinal cord injury in Connecticut with delineation of incidence, cause, evaluation of treatment; cost comparison of treatment in an organized SCI center and community hospitals in Connecticut, and determination of when stability of neurological function occurs; studies of animal models of spinal cord injury, evaluating various treatment modalities, effects of trauma on spinal cord blood flow, and metabolism; determination of spinal column stability including

computer models of primate spinal column; post-traumatic alteration in blood-spinal cord barrier; the effect of biogenic amines on the resulting neurological dysfunction and ultrastructural analysis of the effect of impact trauma; the development and study of a model system in the Larvil Lamprey (Petromyzon Marinus) for study of regeneration in the central nervous system; a study of the formation of peripheral neuroma and the factors controlling its size; and, study of the olfactory bulb re-establishment of central synaptic connection post-injury.

Program of Research in Spinal Cord Injury

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Sponsor: National Institutes of Health

Purpose — This program is concerned with multidisciplinary studies of the consequences of experimental spinal cord injury. Four of the five projects involve physiological, biochemical, and pharmacological studies of descending locomotor control mechanisms in cats and monkeys. The fifth is a study of the process of axonal myelin disintegration after blunt trauma to the spinal cord, with special interest in endogenous degradative enzymes.

Fundamental Studies in Spinal Cord Injury

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Sponsor: National Institutes of Health

Purpose — The primary objectives of this proposal are to: 1) correlate alterations in the somatosensory evoked potential (SEP) with specific spinal cord lesions; 2) study the electrophysiological alterations occurring in the SEP following graded trauma; 3) study the effects of trauma and the influence of other agents on the isolated *in vitro* spinal cord; and 4) develop and test methods of computer analysis for the rapid recognition, differentiation, and characterization of SEP's.

Progress — Methods used entail the following: 1) measurements of amplitude, latency configuration, and Euclidean distance; 2) the use of a standard weight drop apparatus to produce trauma; 3) the use of the recorded far-field potential to determine its effectiveness as a reliable measure of spinal cord trauma; 4) use of an *in vitro* spinal cord model to separate effects of mechanical trauma from ischemia-induced necrosis resulting from impaired microcirculation; 5) development of a reliable model to mimic spinal cord trauma; and 6) continued development and application of computer analysis for SEP classification.

A Feasibility Study on Detection of Impending Pressure Sores Using Ultrasound

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The objectives of this study are to develop ultrasonic techniques to assess the state of superficial and deep tissues with respect to early changes that signal the incipient development of tissue breakdown as well as changes during the healing process.

Progress — This study has approached the problem by means of an experimental model in pigs. Tissue damage in pigs is created by applying a constant force

through specially shaped indentors under the control of a microprocessor. This model is employed to create a known degree of tissue damage on which specific acoustic parameters can be measured for comparison to normal. Acoustic parameters, namely, attenuation and integrated backscatter, will be measured over normal and pressure damaged tissue or regions utilizing an ultrasonic pulse echo system. An IBM instrumentation computer is used for acquiring and processing ultrasonic data. Reflected ultrasonic data are sampled at 50 mHz using a Biomation 8100 A/D converter. Correlation of acoustic parameters with histology of pressure damaged tissues is laying the groundwork for future development of a routine noninvasive, clinical ultrasonic test that could warn of impending pressure sores and whether the changes were occurring in deep or superficial tissues.

Clinical problems associated with the effects of mechanical pressure on soft tissue represent one of the great challenges in the management of handicapped individuals. Due to the high cost of care and management of patients with pressure sores, it is important to gain further understanding of their etiology, and to develop techniques that permit early prediction or detection of impending tissue breakdown in time to take corrective action. Prediction of risk from pressure sores is based on measurement of external factors (such as interface pressure), but predictions are unreliable within tissue. Furthermore, external measurements do not monitor the actual state of the tissues, yet patients react differently to similar environmental conditions. Detection of incipient pressure sores implies some direct means of measuring the actual condition of the tissues. This study is investigating the feasibility of utilizing ultrasonic techniques for this purpose with special reference to deep tissues.

The Biofeedback Incontinence Training Program

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Sponsor: VA Rehabilitation Research and Development Service, Olin E. Teague Veterans Center

Purpose — The principle of biofeedback is defined as the use of electronic equipment to reveal specified physiological events to the individual. Control of otherwise involuntary events is learned by manipulation of the electronic feedback signals. In this case, electromyography (EMG) is used to monitor muscle activity at the rectal sphincter. The urinary and external anal sphincters are by design two halves of a figure eight of muscle tissue. By collecting data on the contractile activity of the more superficial muscle at the anus, correlated activity of the bladder sphincter is known. With this tool for physiological awareness, the subject can exercise selectively the target/problem muscles. Increased muscle tone and control of sphincter function aids in the control of urine flow/leaking.

Progress — Approximately 25 individuals were referred to the investigator as having urinary incontinence. Of these, ten met the overall criteria for the study and completed the treatment program. The participants' ages ranged from 57-78 (M = 67) and were ambulatory and self-care. Some of the subjects managed the leaking urine with pads; others utilized external urine collecting devices.

Subjects were interviewed by the investigator to determine if each met the criteria of the study and to obtain a health history regarding incontinence. Selected subjects were asked to maintain a two-week record of bladder leaking

urgency for baseline information. Biofeedback treatment sessions were scheduled at two-week intervals and consisted of review of the current bladder record and practice of sphincter exercises while attached to the EMG recorder. Subjects were instructed to perform the simple exercises on a daily basis.

Preliminary Results — Ten subjects completed the B-FIT Program (urgency n = 3, stress n = 2, p-surgical n = 5). The subjects with urgency were able to decrease the frequency of urges to within normal limits and thereby control leaking episodes. The stress incontinent subjects were able to decrease leaking by 66 percent and 88 percent. The three post-surgical subjects were able to decrease leaking by 75 percent, 75 percent and 79 percent, respectively. The two post-surgical subjects had been incontinent for more than 20 years and did not respond to the intervention.

The results of this study reinforce the importance of assessment of bladder and bowel habits to determine the type of urinary incontinence to be treated.

Residual Bladder Volume Determination for Spinal Cord Injury Patients

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Sponsor: VA Rehabilitaton Research and Development Service

Progress — During the past year we have: 1) completed our laboratory testing with our prototype system; and 2) used those results to modify and simplify our data sampling process and to develop a post-processing algorithm for improved accuracy. The simpler, improved approach has given an average accuracy of better than eight percent with a standard deviation of five percent for 15 subjects with volumes between 50 and 300 cc. Further post-processing improvements are now being incorporated. The final design of all components for the clinical prototype system have been completed, all individual components have been checked, and the prototype system is being put together for interface checks and clinical tests in Fall 1986.

The Spasticity of Spinal Cord Injury

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — This research utilizes electrophysiologic testing of spinal reflexes to examine the neurophysiologic changes which accompany the appearance of spasticity following spinal cord injury (SCI). The objectives are: 1) to describe the temporal course of reflex changes both for stretch reflex and withdrawal reflex pathways after SCI; and 2) to correlate electrophysiologic measures of spinal reflex activity with clinical assessments of hyperreflexia.

Progress — Electrically-elicited Hoffman (H) and mechanically-elicited tendon (T) reflexes, electrically-elicited withdrawal reflexes and direct muscle (M) responses are recorded serially through one year following acute spinal cord injury. Cauda equina afferent and efferent potentials that accompany the H and T reflexes also are recorded. Measures of reflex excitability include H/M and T/M amplitude ratios for the muscle potentials and efferent/afferent ratios for the cauda equina potentials.

Methodologic observations in control subjects reveal that placement of recording electrodes overlying the calf muscles markedly influences the H/M ratio and that placement well above or below the gastrocnemius-soleus junction minimizes excessive serial variation due to technique. In acute SCI patients, a characteristic time-course of H reflex changes is seen with H/M ratios increasing transiently between one and four weeks and again between two and five months. This latter increase in H/M ratio is due to an increase in H reflex amplitude rather than a decrease in M response amplitude. Yet to be addressed in this research is the assessment of stretch reflex excitability by using cauda equina potentials and the temporal course of withdrawal reflex changes.

Evaluation and Rehabilitation of Reproductive Function in Paraplegia

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Sponsor: VA Rehabilitation Research and Development Service

Progress — Efforts have been directed over a period of nine years to develop methods and equipment for assessment of the reproductive potential of male paraplegics. Rectal probe electrostimulation equipment has permitted the delivery of appropriate electric current, with complete electrical safety, to elicit erection and seminal emission. The problem of retrograde seminal fluid flow into the bladder has been investigated via studies involving various catheter designs and balloon inflation pressures to block the bladder neck. Testicular biopsies, profiling of serum reproductive hormones, and semen evaluation (of sperm motility and morphology) also have added to our knowledge of the overall reproductive status of these patients.

We have carried out 79 studies on 38 spinal cord injury patients. Intolerance to adequate current delivery for erection and seminal emission was common among patients with cauda equina lesions. Seminal emissions were obtained from 58 studies in 73 percent in these 38 patients. Total sperm count was variable; in 42 studies (79 percent), it was greater than 20 million. Sperm progressive motility usually was low; in 83 percent of the 58 emissions, it was less than 20 percent. Efforts are being directed to study and improve sperm motility of seminal emissions in order to fulfill the ultimate goal of this project, which is the effective use of collected sperm from paraplegic males in insemination for siring normal children.

Devices for Female Urine Incontinence

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Urinary incontinence, both a medical challenge and a social embarrassment, afflicts five to ten million Americans. An external urine collection device for women, comparable to the condom-type catheter for men, is not commercially available. Currently available noninvasive products for management of urinary incontinence in women are inconvenient, their use is associated with socially unacceptable odors, and they are confining and frequently ineffective. The customary method for management of urinary incontinence in women, the indwelling catheter, invariably leads to bacteriuria which may be the

most common nosocomial infection in this country. As a viable alternative to the indwelling catheter, an external urine collection device for women must be effective in managing urinary incontinence, have a high degree of patient acceptance and have the potential to decrease the incidence of bacteriuria and its sequelae. Such a device would likely reduce health care costs and prevent otherwise unnecessary institutional admissions.

Progress — The Infectious Diseases Research Laboratory at the Baltimore VA Medical Center is conducting clinical evaluations in women to determine efficacy of prototype external urinary incontinence devices. Initial clinical studies in non-ambulatory women have evaluated device efficacy for five consecutive days of wear time. Results from these short-term clinical trials indicate that prototypes are easy to apply, are effective in managing urinary incontinence [average wear time of 29 hours while containing an average urinary output of 1,500 cc without leakage], and have excellent patient acceptance. Adverse reactions have not occurred. Continued evaluation, using design modifications suggested from results of initial studies, will focus on efficacy of devices for extended wear times and in ambulatory patients.

Spinal Cord Explants Cultured on Carbon Filaments and Stimulated with Direct Current

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Sponsor: Paralyzed Veterans of America, Vaughan Chapter

Purpose — Following complete spinal cord transection in mammals, nerve fibers above the transection begin to regrow, but, this growth is usually transient. It has been thought that the environment at the site of the injury was unfavorable to growing and regenerating axons. Many investigators have attempted to modify the microenvironment to make it more favorable to nerve fiber regrowth. One of these ways has been to stimulate regrowth with minute electric currents. But, the process of axonal regeneration alone is not sufficient for functional recovery. The growing axons must be guided and directed to their proper destination.

A few laboratories have reported successful implants of carbon filaments as substitutes for injured ligaments and tendons, in both experimental and clinical studies. Carbon filaments provide mechanical strength and act as a scaffold for the development of new aligned fibrous tissue. The filaments eventually degrade as the new tissue matures.

Progress — This study was designed to evaluate the influence of carbon filaments on the growth and orientation of nerve fibers from spinal cord explants *in vitro*. For this study we designed a petri dish in which we attached approximately 3000 carbon filaments (8 to 10 μm diameter) to the bottom of the dish with their free ends extending through and beyond the dish. We then sterilized the entire assembly. We placed spinal cord explants on the carbon filaments, with the free ends of the filaments attached to a 0.2 μamp direct current source.

We prepared spinal cord explants consisting of one to two millimeters thick thoracolumbar cord segments from 15- to 17-day-old rat embryos under sterile conditions. All explants were grown for three weeks in Dulbecco's modification

of Eagles medium supplemented with fetal calf serum, glucose, and penicillin-streptomycin at 37 degrees Centigrade in a humidified 95 percent air and five percent CO_2 atmosphere. At the end of three weeks we rinsed all culture dishes with physiological saline. Using an ocular micrometer, we measured fibrous outgrowth from the edge of the explant to its most distal point.

We observed healthy explants after three weeks in culture. A scanning electron microscope (SEM) showed us that outgrowth from explants was parallel to the longitudinal axis of the carbon filaments. Neurites from the explants were growing on and in between the carbon filaments. The outgrowth we observed with SEM appeared to be both nerve fibers (when stained with silver protargol method) and glial fibers (when stained with immunoperoxidase method). In electrically stimulated explants, neurite length was greater towards the negative pole.

We believe that the carbon filaments provide support and guidance for the growing fibers from the spinal cord explants in tissue culture. A 0.2 μamp constant current passed through the carbon filaments enhancing fiber growth.

Neural Mechanisms Underlying Bladder Dysfunction After Spinal Trauma

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Purpose — This project's goal is to learn more about the underlying mechanisms of bladder dysfunction following spinal trauma and to use this knowledge to develop ways to enhance the recovery of bladder function after spinal trauma. It compliments our other studies, which focus on ways to overcome paralysis in humans.

Progress — We have two objectives for this project: 1) develop an animal model to study micturition dysfunction after spinal trauma, and 2) use this model to study the effects of various drugs on the spinal control of micturition. We chronically measure the relationship between bladder volume and pressure before and after the spinal administration of opiate agonists and antagonists, and before and after spinal trauma, using pairs of ultrasonic crystals that have been implanted in the bladder wall and a miniature pressure transducer implanted into the bladder.

Our research should lead to a better understanding of the neurophysiology and neuropharmacology of bladder function because we can measure and manipulate many of the neural and muscular events underlying bladder function in the unanesthetized animal. Such understanding is needed because renal complications remain the number one cause of death during the long-term management of the spinal cord injured patient. These complications are a direct result of the bladder dysfunction that almost always accompanies spinal cord injury.

C. Spinal Cord Regeneration

Axon Regeneration in the Mammalian Spinal Cord in Response to Surgical Denervation and Nerve Growth Factor

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Purpose — The objective of this project is to perform dorsal rhizotomies to quantitate sprouting of axons in Lissauer's tract and in the dorsal columns.

Progress — In order to assess sprouting of intrinsic nerve processes in Lissauer's tract, the sensory axons were surgically removed unilaterally by a series of dorsal rhizotomies. To do this, 200 to 250 gram male and female rats were anesthetized by an intraperitoneal injection of sodium pentobarbital (40 mg/kg). A unilateral laminectomy was done either on the left or the right side, the dura and arachnoid membranes opened and dorsal roots of thoracic segments T4 through T9 were identified and cut. A combination of frequent H_2O_2 (three percent solution) application and gel foam was used to minimize bleeding.

Following surgery, a strip of Dow corning Silastic sheeting (subdural implant material) was placed on top of the exposed spinal cord and roots, the musculature was sutured and the skin incision was closed by autoclips. After this procedure, the rats were usually eating and drinking within one hour. The rats are surviving well and will be allowed survival time of one month, three months, and one year at which time the dorsal rhizotomies described above will be repeated acutely.

To assess sprouting in the dorsal columns, the surgical procedures were as described above but the chronic and acute dorsal rhizotomies were performed for segments L1-L6, S1-S4 and C1-C3. These surgeries are still in progress.

Trophic Interactions Between Nerve Terminals and Their Target Tissues

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Purpose — The focus of this research is to study the trophic influences exerted by normal nerves upon the cell population of their target tissues, and the changes that occur after damage to the nerve. The mammalian taste bud and its gustatory nerve supply is being used as a model tissue for these studies.

The taste bud exists as a collection of elongated cells situated amidst the epithelial cells of the tongue. The dependence of the taste bud cell population upon its gustatory nerve supply is extraordinary. Serving the gustatory nerve supply is extraordinary: severing the gustatory nerve results in degeneration of the taste bud cells and disappearance of the taste bud. When the nerve regenerates (nerves outside the spinal cord have this ability), the taste buds are reconstituted from the epithelial cell. This is in contrast to the case of a muscle after damage to its motor nerve, where the muscle cells do not regenerate upon regeneration of the nerve. Furthermore, the taste bud cells normally have a relatively brief lifespan. The cell population of the taste bud is constantly being renewed by differentiation and migration of cells from the surrounding epithelia, and this turnover of cells

also is thought to be under the direct influence of the gustatory nerve. Thus, the taste bud cell population and its gustatory nerve supply represents a powerful model for studying neuronal trophic mechanisms that are important for maintaining the integrity of a target when its nerve supply is intact, and for rejuvenating a target when its nerve supply is restored after damage.

The data collected in these studies will represent the first precise quantitative analysis of trophic regulation on a target cell's turnover rate by its nerve supply, and thereby provide new information essential to future studies on the identification of the factor(s) responsible for this control of growth.

Progress — Results from the project to date have been encouraging. The point at which new cells enter the taste bud has been described, as well as their later movement as they mature and eventually are lost. The nature of the maturation process itself, which can be likened to a shortened process of development and aging, also is beginning to unfold. These initial studies on animals with an intact nerve supply are progressing well, and the outlook is good that planned denervation experiments (severing or crushing the gustatory nerve) will be undertaken soon. These experiments will provide enlightening. Indeed, comparison of the results from intact animals with those from denervated animals will be tantamount to an understanding of the manner in which nerves and their targets interact to maintain a viable, functioning system.

Studies of CNS Regeneration: Changes in the Astrocyte Cell Surface Membrane Following CNS Injuries and During Development

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Purpose — When axons in the adult mammalian Central Nervous System (CNS) are injured, they undergo regenerative sprouting, but these sprouts fail to grow for more than a few millimeters. The inability of injured CNS axons to grow for long distances in order to reach their appropriate target cells may be largely responsible for the many functional deficits seen following injuries to the adult mammalian brain and spinal cord. On the other hand, when peripheral nerve axons are injured, they can successfully regenerate for considerable distances. This capacity for axonal regrowth in the Peripheral Nervous System (PNS) is believed to be due in part to the longitudinally arranged columns of Schwann cells (non-neuronal cells).

Recent transplantation studies have demonstrated that CNS neurons located in many different areas of the adult mammalian brain and spinal cord are capable of extensive axonal growth through peripheral nerve grafts. These and other studies suggest that the differences in the regenerative responses in the injured PNS and CNS may be more dependent upon the non-neuronal glial environment surrounding the injured axons than upon the neurons alone.

The nervous system may be divided into neuronal and glial compartments. The glial compartment in the CNS consists of three types of cells—astrocytes, oligodendrocytes, and microglia. Of these glial cell types, the astrocytes may play a crucial role in the response of the CNS to injuries.

Neuron-glial interactions also are believed to be important for many develop-

mental events. In contrast to the extensive axon growth that occurs normally in the CNS during development, axon growth is minimal in the injured adult CNS. These differences may be due to glial changes that occur during development or in response to CNS injuries. Such changes might be expected to occur in the cell surface membranes, which are sites where neuron and glial cells interact.

The investigator proposes to study the changes that might occur in the cell surface membranes following CNS injuries and during development. This will be accomplished by generating momoclos antibodies to various components of the cell surface membranes. These antibodies will then serve as markers to identify which molecules change in response to CNS injuries and whether such molecules play any role in the regeneration of axons.

Axonal Regeneration in the Adult Spinal Cord

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Purpose — Spinal dorsal root axons return sensory information from skin, muscle, the descending colon and rectum, the sex organs, and the urinary bladder back to the spinal cord and the brain where sensations are consciously perceived. More importantly, this sensory information is essential to the reflex functioning of these organs. To spinal cord injury patients this information is particularly important as they depend on these visceral reflexes to carry out bodily functions.

Researchers have looked at the problem of dorsal root regeneration in mammals and for years their studies report that the dorsal root axons do not reenter the spinal cord due to barriers formed by the glial cells, the supporting cells of the central nervous system. Recently, however, a technique using an axonal tracer, horseradish peroxidase (HRP), which labels regenerating axons, has shown that cut or crushed dorsal root axons in adult frogs regenerate into the spinal cord where they are able to grow and reestablish connections. Previous studies found that some axons can actually regenerate into the spinal cord of cats and make functional connections if they are routed through a dorsal root. This observation has been confirmed and extended by using the axonal tracer HRP.

These studies are particularly important because they suggest that the glial barrier, which has been reported to prevent dorsal root axons from reentering the cord, is not an impenetrable barrier to all axons. Moreover, they show that once axons have penetrated the central nervous system, their growth is supported by the environment of the adult mammalian spinal cord.

Progress — For the past two years HRP has been used to study the regeneration of different types of axons into and within the adult frog spinal cord. The work indicates that some regions of the adult frog spinal cord differ with respect to their ability to support axonal growth. Electron microscopy shows that regions of the adult frog spinal cord that more closely resemble the embryonic or developing spinal cord appear to be more supportive of axonal regeneration.

Although work to this point has used the frog as a model for axonal regeneration, work is now extended to a study of regenerating dorsal root axons in adult rats using HRP where greater sensitivity of the HRP reveals a small number of regenerating axons missed with previous techniques. Different types of glial

cells in the spinal cords of frogs and rats also will be studied. By using antibodies that specifically label different types of glial cell, those of the frog and the rat will be compared and types that respond to dorsal root injury in the two species will be identified. This may explain why a greater number of dorsal axons regenerate in the frog.

It is hoped that this research will lead to other studies directed at ways to increase the chances of individual axons entering and growing within the spinal cord.

Protein Transport in Injured CNS Axons

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Purpose — Corticospinal axons, those fibers connecting the motor cortex region of the brain to the output neurons in the spinal cord, control the voluntary movements of the body. When they are injured motor ability is lost since, unlike axons in peripheral nerves which can regrow from the point of injury, corticospinal axons cannot regenerate. The Golden hamster is an ideal model for studies in determining differences in ability of corticospinal axons to regenerate since they can regenerate these axons in the first two weeks of life but not at later ages.

The researcher previously looked at the properties of the corticospinal neurons during the time regeneration is possible and during the periods when it is not to determine the major changes in the cell. Particularly, the studies concentrated on the process of delivery of proteins, known as slow axonal transport, which is directly related to axonal regrowth since it delivers the proteins needed to build a new axon. Transport was compared in normal adult and immature corticospinal axons and it was found that the rates of transport differed between immature and mature axons and that several proteins were absent or present in smaller amounts in the immature axons.

Progress — The researcher hopes to study the changes in protein synthesis and slow axonal transport after an axonal injury, using the previous studies as a baseline in order to identify the signal sent to the cell body after injury. This causes the cell to alter its metabolism making regeneration no longer possible. Some studies indicate that cells capable of regenerating increase the production of certain proteins essential for the reconstruction of an axon and decrease their production of unnecessary proteins.

Adult and immature Golden hamsters will have the spinal cord on one side of the body surgically severed. The hypothesis is: if protein synthesis changes, this will be detected when small amounts of radioactive amino acids are injected into the motor cortex region of the brain (where the nerve cell bodies give rise to the corticospinal axons). The corticospinal neurons will take up the labeled precusor (the amino acids) and use them in synthesizing proteins, which will then be transported into the intact regions of the axons. There the rate and mechanism of transport can be studied as well as any alterations in proteins which were synthesized and transported in injured corticospinal axons.

The researcher hopes to define on a molecular level, for the first time, that the injury response of mammalian CNS neurons during a transition from a stage at regrowth is possible to an adult, incompetent stage. By defining a biochemical response, future attempts to modify the response using pharmacological or genetic tools is possible.

Central Nervous System Regeneration in Nerve Grafts

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Purpose — The objective of the research was to determine some of the factors that govern successful sprouting and elongation of central nervous system (CNS) neurons into peripheral nerve grafts which were inserted into the CNS of an adult rat. Determination of these factors may allow the development of techniques to enhance regrowth of CNS neurons.

Progress — The basic experimental design involved examining the response of CNS axons following their transection under three different conditions. The axons were labeled with wheat germ agglutinin linked to horseradish peroxidase (WGA-HRP) and studied under light microscopy. The distance an axon dies back from where it was cut was called axonal retraction, which appears to be related to the amount of damage an axon sustains after injury. Less severely damaged axons may be more likely to regenerate. The appearance of damaged axons' endings also may indicate their ability to regenerate.

The degree of axonal retraction and the percentage of each type of axonal endings were studied when three conditions were varied: control versus implanted graft; the distance between the injury and the cell body; and time. The control versus implanted graft condition was designed to determine how the presence of a nerve graft alters an axon's response to injury in order to promote axonal regeneration. Varying the distance between the injury site and the neuron's cell body examined whether the axonal response to injury of nearby and distant neurons was correlated to the different probabilities by which nearby and distant neurons enter a nerve graft. The time course of axonal sprouting and entry into the nerve graft was examined to compare it to that seen in peripheral nerves where regeneration is rapid and successful.

1) Axonal Retraction Distance: most axonal endings were found quite close to the lesion site with a smaller number scattered at greater retraction distances. Up to the sixth day following the lesion, no axon was observed to penetrate a nerve graft or to cross the original lesion site.

a) When control and nerve grafted animals were compared under the same distance and time conditions, the amount of retraction was always greater on the control side. Therefore, the graft seems to exert a protective influence on the axonal ending.

b) A small but significant difference in the same direction was observed in graft-implanted rats at six days.

c) There was a clear difference in the time course of axonal retraction between 3 mm and 6 mm lesioned rats. It appears that the more distally transected axons are still retracting while the nearby transected axons have already begun to advance at six days.

2) Ending Types: analysis of the distribution of ending types as characterized by morphological structure under various treatments was undertaken to determine the changes in the proportions of ending types that normally occur with time and to examine what effect the nerve graft has on the distribution. (The types were ball, balloon, beaded, club, lance, and sprout. In all conditions the major ending type was the ball ending. Of particular interest was the distribution of sprouting endings since such endings are often taken as the initial sign of the initiation of regeneration).

a) At day one, the distribution of ending types was similar for both control and graft cases with ball endings predominating and club endings numerous. At six days, the proportion of ball endings increased but sprouting endings decreased. Thus, the graft does not seem to promote axonal elongation by increasing the proportion of sprouting axons.

b) Based on comparison of 3 mm and 6 mm lesions, the graft does not differentiate between nearby and distant neurons on the basis of promoting differential sprouting. Definite changes in type distribution occur in time with the proportion of sprouts rising dramatically (3 to 5 times) between day one and three and may start as early as three days.

3) Loss of Axonal Endings: a major observation is the dramatic decrease (50 percent) in the number of labeled endings between days one and six. A 50 percent decrease in the number of labeled axons is quite consistent with observations of cell death following axonal section.

4) Axonal Diameter: two of our observations confirmed that larger diameter axons show greater retraction following injury than small diameter axons. Also, at six days, most of the remaining axons appeared to be of a smaller diameter.

Preliminary Results — 1) Intrinsic control of CNS neurons to axonal lesions at different distances is in the appropriate direction to explain the observed differences in axonal regrowth. 2) The nerve graft produced two clear effects—it retards the normal amount of axonal retraction following injury, and the graft alters the proportions of ending types in comparison to controls in as little as six days.

The ways in which the graft does not increase regenerative responses are also instructive. The graft does not increase growth by reducing apparent cell death nor does it appear to increase the regenerative potential of CNS neurons by shortening the initiation time or by increasing the frequency of obvious sprouting.

Functional Spinal Cord Regeneration (Cats)

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Sponsor: National Institutes of Health

Purpose — Our laboratory is devoted to the study of functional regeneration in the mammalian spinal cord. The model system under study is the spinal cord of the adult cat. Specifically, this project investigates the possibility that spindle group II afferents may generate new functional connections with spinal motoneurons. Synaptic sites are made available on these motoneurons as a consequence of temporary ischemia of the spinal cord, eliminating interneurons normally occupying about 95 percent of all synaptic sites on motoneurons.

The fundamental question asked is whether spindle group II afferents sprout to form new functional contacts in response to the presence of newly available synaptic sites in the post-ischemic spinal cord. The existence of new group II-motoneuron synapses would be suggested by the presence of single fiber spindle group II EPSPs of unusually large magnitude (greater than 100 uV) or in an unusually large number of motoneurons (the percentage will depend upon the conduction velocity of the particular afferent). In addition, a number of other important questions will be asked concerning neuronal function in the post-traumatic cord: are single fiber EPSPs then different in configuration (indicative) of altered synaptic location on the soma-dendritic membrance)? Are different types of motoneurons contacted? Are denervated motoneurons more or less excitable (rheobase, repetitive firing properties)?

Recovery and Regeneration After Spinal Neuron Injury

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Sponsor: National Institutes of Health

Purpose — The program project supports an interdisciplinary series of projects on the mechanisms underlying the effects produced by severing afferent or efferent connections to or from neurons of regeneration sprouting and/or reinnervation. The purposes of the programmatic approach are: 1) to stimulate interaction and collaboration by investigators from four departments of three institutions; and 2) to support shared facilities at the University of North Carolina.

The seven projects are directed at: a) the relation of behavioral recovery to the regeneration of long-descending tracts after spinal cord section; b) possible synaptic reorganization in ascending sensory systems after spinal chordotomy; c) central consequences (neuronal degeneration and death) after peripheral sensory fiber injury; d) the sensory and efferent consequences of chronic renal denervation and reinnervation; e) the modifications in effector organ (skeletal muscle and kidney) or sense organ behavior following spinal nerve injury and regeneration; and f) biochemical changes in spinal motoneurons following injury and regeneration.

Muscle Reinnervation and Neurotrophic Influence (Anurans, Rodents)

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Sponsor: National Institutes of Health

Purpose — The physiological properties of the spinal cord and its regenerative capacity will be studied in mammals rendered paraplegic by transecting the spinal cord at T5 or by injecting 6-aminonicotinamide, batrachotoxin, or tetrodotoxin into the subarachnoid space. Spinal reflexes, neuromuscular transmission, and membrane properties of slow and fast muscles will be measured to determine: 1) the effect of drugs and toxins that inhibit gliosis; 2) the effect of hibernation (in which glial and connective tissue scarring is suppressed); 3) the effect of toxins which alter the ionic composition of the extracellular space surrounding the neurons; and 4) the effect of the hibernating (sleep) factor on the physiological and regenerative properties of the neuromuscular systems of nonhibernating mammals.

The relation of axonal transport to the maintenance of the membrane properties of slow and fast muscles will be examined.

The interaction between the dystrophic gene and neurotrophic influences will be examined in dystrophic chicken muscle during denervation, reinnervation, and hyperinnervation. The effect of pumiliotoxin (which we have found to suppress the symptomatology of the disease) will be studied.

Drugs and toxins such as amantadine, naloxone, quinacrine, atropine, piperocaine, batrachotoxin, gephyrotoxin, pumiliotoxin, and histrionicotoxin will be used to probe the function of the ACh receptor-ionic channel complex.

Progress — Isolation and purification of the ACh receptor and ionic channel proteins have been sufficiently accomplished in our laboratory to enable us to attempt to reconstitute these macromolecules in artificial lipid membranes. Ionic permeability of these functional, ion-conducting membranes will be assessed as well as the effects of receptor and channel-blocking drugs such as those named.

D. Independent Living for the Severely Disabled

Promoting Consumer Involvement

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Sponsor: National Institute of Handicapped Research

Purpose — Teaching consumers with severe disabilities new ways to improve their community and its services is a promising approach to promote independent living. In the past three years, the investigators have developed and evaluated the Concerns Report Method. This unique self-help method allows disabled citizens and their families to assess, prioritize, and convey their concerns to decision makers.

Progress — To date, nearly 2,000 disabled residents have used the Concerns Report Method to establish priorities for independent living services. These include over 500 persons with disabilities in nine different local applications in Kansas and Missouri. Another 1,400 Kansas residents with severe disabilities participated in a related project that set a statewide action agenda. Approximately 4,000 additional disabled citizens were identified as participants in current applications in Washington, D.C. and Los Angeles.

Preliminary Results — This information helps organizations and decision makers identify concerns and consider potential solutions from the perspective of consumers. State, regional, and national data will be combined to provide a profile of the concerns of disabled consumers. These reports can be used by elected officials and service providers to better utilize existing resources to meet the needs of their constituents.

Future Plans — We plan to expand use of the Concerns Report Method with new projects throughout the country. Additional applications are planned for Des Moines, IA; Columbia, MO; Wichita, KS; Norfolk, NE; Salt Lake City, UT; and Missoula and Helena, MT. The Method will be used to establish service priorities in these or other sites as requests for this unique planning tool are met.

Involving Disabled Consumers in Community Change

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Sponsor: National Institute of Handicapped Research

Purpose — Many community decisions affect individuals with disabilities and their families. For disabled persons to achieve equal opportunities they must assume leadership roles in their community. Research on consumer leadership and advocacy is designed to help consumers organize into small groups to monitor ILC operation and community affairs.

Progress — Project staff have prepared self-help guides on how to identify, select, report, and discuss issues; lead group discussions; and take action on issues. Procedures for establishing effective consumer groups and training current and new members also have been prepared, evaluated, and disseminated to interested consumer groups.

To effectively take action on an issue requires that the group understand the range of potentially successful actions that can be taken. A hierarchy of 25 possible actions, appropriate for use by consumer organizations, has been identified. These actions allow consumer groups to make recommendations and participate in decisions about issues affecting them.

Future Plans — Field tests of these procedures have already contributed to a number of changes in local ILC programs and city policies. Project staff plan to implement and evaluate the consumer involvement model with six additional consumer groups during the next 18 months.

Training Attendant Care Management Skills

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Sponsor: National Institute of Handicapped Research

Purpose — Attendant care is a vital service for many people with disabilities who live independently. Until now, there has been no empirically-based model for teaching consumers how to train and manage an attendant.

The investigators have adapted management techniques that have been successful in other settings for use in attendant care. These techniques address two common management problems—lack of job specificaton for attendants and inability to provide objective, corrective feedback on attendant's work performance.

Progress — Performance checklists are used to provide instructions to caregivers in how to conduct routines. They also allow consumers to monitor, evaluate, and

provide feedback to caregivers on their performance. Once training is complete the checklists are used to maintain consistent performance.

The training and management procedures have been field-tested with consumers and a training manual for consumers has been completed. Project staff are now working on complementary materials to train ILC staff to implement the consumer training program in their own setting. Plans for the next year include field-testing the complete procedures package in two settings.

Encouraging Dignified Service Provision

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Sponsor: National Institute of Handicapped Research

Purpose — People with disabilities frequently must deal with human service agencies, such as local welfare offices, that can be insensitive to their needs. From applications of the Concerns Report Method, we have identified a perceived lack of courtesy in service provision as a major concern of people with disabilities.

Progress — The investigators have outlined a research study to address this issue. The study entails developing an assessment protocol for consumer groups to monitor the degree to which human service agency personnel treat them with dignity. Consumers are then provided with strategies for encouraging more dignified treatment, when appropriate. Working with local consumer groups, the investigators will specify the behaviors involved in providing dignified treatment. Improving courtesy and respect shown to disabled consumers should increase satisfaction with human services, and this will, in turn, support efforts by persons with disabilities to live independently.

Promoting Community Support for Independent Living

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Sponsor: National Institute of Handicapped Research

Purpose — A top concern for independent living technology development is how to enlist community support for issues related to independent living. Most ILCs agree it is essential to gain community support and their current efforts could be more successful.

Progress — The investigators have initiated a research program to identify, develop, validate, and disseminate procedures to promote community support for independent living. Based on information provided by ILCs, information packages designed to educate the public and promote community support will be prepared. For example, a model slide presentation on the services provided by a local ILC might be prepared. It would include an overview of the program's philosophy, a description of the agency's consumers and staff, and information about each service provided by the agency. Similarly, model information packages might be prepared for radio and television public service announcements, brochures describing the center's services, and newspaper press releases.

Each model information package will be based on a task analysis designed to identify the critical components of the package. The task analysis will be based on interviews with successful programs and a review of the literature. The task analysis phase will produce a tentative sequence of responses designed to communicate information effectively.

Finally, self-help guides will be prepared to allow ILCs to adapt model information packages for their own use. For example, a written guide on adapting the model slide presentation might include chapters on how to edit a presentation script to describe local services and concerns, how to develop the slide program, how to deliver a scripted slide presentation, how to evaluate the impact of the presentation on an audience.

Each self-help guide will be pilot-tested under analog conditions to determine its effects on teaching people how to adapt model informational packages. This evaluation will provide an opportunity to modify and revise procedures before they are disseminated to ILCs.

Improving Media Portrayals of Persons with Disabilities

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Sponsor: National Institute of Handicapped Research

Purpose — Media professionals are in an ideal position to shape the public image of people with disabilities. Their capacity to communicate ideas and present appropriate models is unequaled in our society. Yet, the media have been criticized for perpetuating stereotypes through inaccurate portrayals of disabled people.

Inaccurate portrayals may persist because of no clear guidelines indicating preferred style and terminology for writing and reporting about disabilities. In response to recommendations from the RTC/IL Advisory Board and consumers nationwide, RTC/IL staff developed a pamphlet, "Guidelines for Reporting and Writing About People With Disabilities." It was compiled with input from over 50 national disability organizations and represents consensus opinion on acceptable terminology and portrayals concerning disability issues. Response has been phenomenal, and over 30,000 copies have been disseminated to disability organizations and service agencies throughout the country.

Progress — The Guidelines were submitted to the boards of editors of Associated Press and United Press International for possible inclusion in upcoming editions of their stylebooks. This would help establish national policies on use of disability terms and portrayals. But, in addition to national policies, consumer groups need strategies to influence portrayals by their own local media to help ensure adoption of an adherence to established guidelines. The investigators have initiated a program of research to develop and evaluate strategies to influence local media. Working with consumer groups in three cities, project staff will examine several strategies, including monitoring and providing feedback on the appropriateness of media features about disabled persons, and providing commendations and awards for exemplary media portrayals. The most effective intervention strategies will be packaged for dissemination to consumer groups in additional communities.

Evaluating the Impact of ILCs

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Sponsor: National Institute of Handicapped Research

Purpose — Independent living service providers and policymakers need valid, reliable, and economical methods to evaluate the impact of ILCs. The goal of the program evaluation project is to develop and field-test evaluation standards that can be used by ILCs. As a preliminary step, investigators have developed methods to measure attainment of consumer goals, ILC impact, and removal of handicapping conditions within the community.

Progress — In the next year, the validity and reliability of these measures will be examined, and protocols will be established for use of these measures to conduct internal and external evaluations of ILCs.

Extending Independent Living to New Populations

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Sponsor: National Institute of Handicapped Research

Purpose — ILCs may be instrumental in assisting mentally retarded persons with the transition to community living. However, ILCs have limited expertise in serving mentally retarded persons. This project will examine the feasibility of extending services to mentally retarded persons and determine problems and benefits associated with serving this population. A survey of ILCs will be conducted during the first year of the project in order to: 1) determine the extent to which ILCs provide—or are asked to provide—services to mentally retarded persons; 2) determine common problems in serving or reasons for not serving mentally retarded persons; and 3) identify ILCs that successfully serve mentally retarded persons and determine the reasons for their success.

Future Plans — Based on the results of this survey, future objectives for the project are to: 1) develop and evaluate training materials for ILC staff so they are better equipped to provide services to mentally retarded persons; and 2) develop or adapt IL services so they may be extended to include mentally retarded persons.

Social Support Systems for Enhancing Independent Living

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Sponsor: National Institute of Handicapped Research

Purpose — Self-help and social support have been major components of the IL movement. For many disabled citizens, ILCs are their primary social support system. Research analyzing social support systems is limited. Available literature primarily focuses on either theoretical discussions about the importance of social support or descriptions of individual support programs. There is little research demonstrating the effectiveness of such groups, in general, or their role in promoting independence of disabled persons, in particular. In the IL field, research is needed to determine: 1) the prevalence of social support systems for people with disabilities; 2) the relationship between social support groups and

ILCs; 3) characteristics of successful support systems; and 4) procedures needed to enhance social support group effectiveness.

Progress — The investigators plan a research project to gather this information. Survey information from ILCs throughout the country will be used to: 1) create a national directory on self-help social support groups for people with disabilities; 2) identify the characteristics, goals, and objectives of IL social support groups; 3) prepare a national directory of IL social support groups; and 4) identify functional variables that differentiate effective from less effective social support groups.

Future Plans — This information will be used in future years to develop training and technical assistance procedures for assisting ILCs in establishing effective social support groups.

RTC/IL plans a number of training and dissemination activities, in the areas of university training, inservice training and technical assistance, and product development and dissemination. University training will include courses in Human Development, Occupational Therapy, Community Psychology, Journalism, and Industrial and Interior Design. These courses provide an overview of the IL movement and the role of various professions in promoting independent living.

A full-time training associate will join RTC/IL staff next year. The training associate will conduct an annual survey of ILC technology needs, develop training and technical assistance activities to address these needs, and provide training and technical assistance to ILCs. Six regional inservice training workshops are planned. Additional, on-site technical assistance will be provided to ILCs as resources permit.

An IL leadership training program has been proposed wherein disabled persons will receive scholarships to pursue academic training and field-based practica. The program is intended to provide talented disabled persons with training and experience needed to assume leadership roles in the IL movement. Scholarships will be provided to three candidates next year, if resources permit.

Technology to Enhance Independence of Physically Disabled School Children

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Sponsor: Rehabilitation Engineering Department, Regency Park Centre for Young Disabled

Purpose — A recent study has shown the majority of children at the Regency Park Centre Special School experience problems with classroom skills, toiletting, and mealtime activities that could be overcome by the application of appropriate technology.

Our purpose is: 1) to investigate the needs established in our earlier study of classroom independence with a view to deciding whether the problems can be solved by commercially available technology or modifications to existing products, or whether a new design is needed; 2) to purchase those products that are available and to design, build, and provide new solutions where necessary; and 3) to measure the extent to which the disabled child's independence has been enhanced by the application of new technology.

Progress — In the preliminary phase the priority problem areas established in our earlier study will be investigated. Where problems have ready-made solutions, those solutions will be implemented. Design guidelines will be established for the new designs that need to be developed.

In the experimental phase designs will be fabricated and implemented with physically disabled children.

During the concluding phase follow-up measurements will be taken regarding the level of independence exhibited by children who have taken part in this project to determine the extent skill deficits have been compensated and independence has been enhanced by the application of technological solutions.

This project will have an industrial designer working with the existing staff of doctors, engineers, teachers, therapists, nurses, and assistants to design and implement solutions for the problems established that have high incidence and technological solutions. Devices will be developed to assist disabled school children with important areas of their lives, including classroom skills, toiletting, and mealtime activities.

The expected outcome is that the children will be made more independent with customized technological support so that some of them will be able to attend regular schools. The project will demonstrate how the introduction of technological innovations for physically disabled children in special schools and mainstream schools can improve the quality of their educational achievement.

Program in Social and Independent Living Skills

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Sponsor: National Institute of Handicapped Research

Purpose — The objectives of this project are to develop and evaluate a comprehensive set of techniques to teach social and independent living skills to chronic mental patients. These techniques are intended to remediate the patient deficits that prevent them from attaining successful community adjustment and living up to their potential for a better quality of life.

A second major project goal is to develop the training technology to maximize its exportability to mental health and rehabilitation practitioners in a variety of clinical and applied settings. The training techniques are to be packaged with very specific instructional materials in the form of patient and therapist manuals and videotaped modeling stimuli to ensure that the materials for each skill content area, called a "module," will be used successfully. They are to be validated within the Social and Independent Living Skills (SILS) Program of the Rehabilitaton Medicine Service at the West Los Angeles VA Medical Center (Brentwood-Psychiatric Division).

Progress — Modules have been developed in several skill areas including conversation skills, leisure-recreational pursuits, grooming, problem-solving, cooking, money management, medication self-management, and homefinding. The modules are designed to have patients: 1) practice the skills that constitute the module within the treatment setting and in the community; and 2) learn structured methods of solving the problems that patients are likely to encounter when using the skills.

Each module consists of a major goal for community living (such as conversation skills, grooming, or recreational activities) and a series of approximately four to eight specific skills related to the attainment of that goal. The skills are taught using a combination of videotaped demonstrations, roleplay procedures, question/answer exercises, *in vivo* exercises, and homework assignments. Special attention is given to the areas of resource management and problem-solving obstacles to successful outcomes that are prerequisites to utilizing each skill and attaining module goals. Each patient participates in a three- to four-month day-treatment program that includes module training as well as case management, crisis intervention, and appropriate liaison with psychiatric and vocational rehabilitation services at the VA Medical Center.

Future Plans — Future research efforts will be directed toward evaluating, field-testing, and disseminating the modules that have been developed. Each module will be evaluated with respect to: 1) *skill attainment*, the degree to which patients are able to successfully demonstrate that they have acquired the requisite skills of the module; and 2) *treatment outcome*, the extent to which the requisite skills are maintained by the patient and generalized to the natural environment.

Rigorously diagnosed schizophrenic patients will be thoroughly evaluated before and immediately after completing the training program. Periodic follow-up measures also will be taken for 18 months. An interpersonal program of five skills areas considered to be critical for attaining successful community adjustment and improving the quality of life will be evaluated. Measures designed to assess improvement in interpersonal skills, problem-solving ability, and social adjustment will be made along with quality of life and psychopathology assessments. The modules will be field-tested at a variety of service settings throughout the United States prior to full scale dissemination.

E. Communication Methods and Systems for the Severely Disabled

MicroDEC II — Environmental Control System and Computer Access Aids

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Sponsor: National Institute of Handicapped Research

Purpose — The MicroDEC II system provides a person with limited motor ability, a common control medium through which electrical appliances, a telephone, and a personal computer can be operated. The system can be controlled remotely via a radio link that can be integrated with a digital wheelchair controller.

The device control features of the MicroDEC II are identical to those of the already commercially available MicroDEC Environmental Control System. The computer access features provide keyboard emulation for Apple II+ and IIe computers. Text creation, as for word processing, is enhanced through innovative

letter and word prediction schemes. In addition to pre-stored commonly used words, the MicroDEC II learns new words as they are spelled by the operator. These words are then incorporated into word prediction algorithm.

Progress — In the last progress report, it was indicated that the research phase of the MicroDEC II was completed and commercial development was being pursued. The MicroDEC II system is now being manufactured by Medical Equipment Distributors, Inc., of Maywood, Illinois, who also manufacture the original MicroDEC. We are presently assisting the manufacturer in the development of support materials.

PACA—Portable Anticipatory Communication Aid

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Purpose — The PACA is a one-year research and development project to design a portable computer communication aid that will enhance the communication abilities of non-vocal persons who also have physical impairments which preclude the use of direct selection techniques. The project has two primary objectives: 1) to augment the utility of traditional scanning communication aids by adding message element anticipation; and 2) to make this scanning communication aid cost effective to the user by capitalizing on the benefits of the innovative technology and competitive marketing of widely available commercial portable computers.

The PACA will incorporate features which address person-to-person (or conversational) communication, note taking, writing, and math calculations. Operation will be available in a single-switch automatic-scanning mode or a two-switch step-scanning mode.

Progress — The aid is being developed around a commercially available portable computer, the Epson HX-20. This computer has many intrinsic features that can be directly applied to the functional requirements of a communication aid, including battery operation, a multi-line dynamic display, a built-in printer and microcassette unit, input ports for switch operation, serial ports for accessory devices such as full-page printer or speech synthesizer, and is a small lightweight size. The HX-20 is also available at low initial cost (relative to dedicated electronic communication aids).

Because the majority of day-to-day communications are novel and cannot be properly effected through pre-stored messages, the focus of the PACA's message creation scheme has been on enhancing spelling and word selection. The Epson's LCD display is used for the presentation of dynamic selection arrays. Numerical linguistic analyses of American-English text are applied to rank message elements on the display according to conditional frequency of use. As selections are made, the aid attempts to anticipate subsequent selections and present those selections to the user in such a way as to increase the efficiency or the rate of message generation. Letters and words with greater probability of being selected are arranged in positions of the selection array that require fewer scanning steps.

In the letter selection mode, letters are arranged in a row-column format based on their probability of following the last selected letter. For word selection, core and learned word lists are accessed by first selecting the initital two letters. The core list is a permanently stored list of the 500 most frequently used American-English words from the million-word Brown University corpus. The learned list, which is initially empty, is filled by words not already in either list but which are added whenever the user spells a new word. Words in the learned list that are not used frequently are dropped in favor of newer words, in order to preserve topical relevance. For instances when pre-stored messages can be used effectively, or for maintaining personal memos, a scheme is provided for labeling, storing and retrieving messages, developed by letter and word selection.

The arrangement and partitioning of message elements and functions in the selection arrays, as well as the interaction between the anticipatory features and the user are being developed with the support of clinic and field trials.

Computer-Aided Motor Assessment and Rate Prediction for Prescription of Communication Devices

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Sponsor: National Institute of Neurological and Communicative Disorders and Stroke, Public Health Service, Department of Health and Human Services

Purpose — A means of determining a potential device user's expert rate as a prescription criterion is needed that will not require a lengthy practice period to measure it directly with each candidate.

Progress — The investigators have developed a system of computer-assisted assessment and calculation procedures which meets this need. It consists of two major components. The first is an objective assessment technique which taps the motor abilities relevant to use of most devices. It is conducted using special-purpose testing instrumentation rather than any specific communication device. It is intended to bypass the *cognitive* demands which would be present in unpracticed use of a device, thereby measuring the *motor* abilities which set an upper limit on rate in expert use. The second component of the system is a computer program which combines the outcome of a client's motor assessment with information specific to the use of each candidate device to derive an estimate of communication rate. Since this estimate is based on data gathered in assessment designed to establish the upper limits imposed on rate by the client's motor abilities, it is referred to as Motor-Determined Maximum Rate, or MDM Rate. In effect, this scheme is intended to model client's performance and its variation with the physical characteristics of devices. It utilizes this model as a means of conducting, in the domain of computer-based estimation, the tests of expert device use which are impossible to perform literally.

Preliminary Results — The assessment and rate estimation methods described above have, at this writing, been developed to the level of working prototypes. Substantial human subject testing has been and continues to be conducted with disabled and able-bodied individuals. Fourteen motor-disabled adult subjects and ten able-bodied controls have participated to date. Etiologies include head injury,

ALS, CP and stroke. Under present and future funding, more detailed experiments and further methodological refinements are anticipated.

In conclusion, it appears to be generally true that, while random variation is greater for motor-impaired than for able-bodied subjects, simple models succeed in extracting the reproducible average aspects of their performance. Reasonably reliable estimators of the dependence of movement time on task variables may be derived from clinically practical amounts of assessment data. This suggests that, while statistical validation of rate predictions remains to be accomplished, clinical feasibility of the investigators' methodology is confirmed.

A Needs-Features Spreadsheet for Communication Device Prescription

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Sponsor: National Institute of Neurological and Communicative Disorders and Stroke, Public Health Service, Department of Health and Human Services

Purpose — Spoken communication becomes difficult and even impossible for substantial numbers of people with neurological conditions which lead to impaired motor function. The large number and diversity of technological aids and personal computers with specialized software and control interfaces, and the real differences among these devices in terms of potential benefit to the disabled individual, have focused increased attention on improving the process of prescribing communication aids.

Progress — As part of this research, a computer-aided system has been devised to guide the clinician in identifying the device or devices which seem to offer maximum communicative benefit for each particular client. This system uses *client* information in the form of answers to an extensive questionnaire concerning the client's needs and preferences; and *device* information, in the form of a lengthy set of quantitative laboratory measurements and ratings, stored in computer disk files.

The output of this system for each client-device pair is a 'Benefit' score, B. The system is intended to be used as a way of evaluating many devices for each client. The B score, then, represents the relative value of each device for that client in terms of predicted communicative benefit. In practice, the assessing clinician enters answers to questionnaire items provided by the client and others and the system prepares a B score for each device the client would be able to use.

The basic tool used by the investigators for representing and manipulating the complex, many-to-many "mapping" of client Needs to communication device Features is a commercially available software package known as Lotus 1-2-3. Development of this worksheet and its clinical application requires, therefore the use of a computer which can run Lotus 1-2-3. We are using an IBM PC but the availability of Lotus 1-2-3 for other personal computers is expanding rapidly.

The worksheet has been tested and adjusted using questionnaire information from 20 non-speaking patients who use communication devices or boards. Measurements of the features of the communication boards and electronic devices used by these patients, in addition to the other devices which we have evaluated so far, constitute the device data files. An experimental study which will test the predictive value of the Needs-Features Spreadsheet along with other aspects of the Tufts-MIT Prescription Procedure began in April 1985.

An Optimal, Inexpensive Text Entry System for the Orthopaedically and Neurologically Disabled

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Sponsor: National Institute of Handicapped Research

Purpose — The goal of this project is to devise a keyboard system based on an inexpensive digitizing tablet and customization via software that will facilitate computer operation by orthopaedically and neuromotorically disabled people. Customization is to be based on results of two lines of research: 1) an investigation of the sensitivity of users' key-to-key time to features of the keyboard's geometry; and 2) an evaluation of techniques of optimization to apply to the features of keyboards identified as important.

Progress — Software has been designed and is now being tested that allows the low-cost Chalkboard Powerpad to function as a field-specifiable keyboard for the Commodore 64, using only commercially available hardware. Keys of minimum ½ inch by ½ inch size are possible as well as selection strategies ranging from encoding and levels to multiple (discontinuous) representation of the same menu item. User-friendly screens are being revised to facilitate keyboard specification by people unfamiliar with computers.

Motor assessment of able-bodied and disabled subjects is being carried out by means of the reciprocal target tapping task and test panel. Previous work supports the hypothesis that inter-key distance and key size and in some cases angle of movement are major determiners of movement time. These data are being reanalyzed to characterize more precisely the effect of angle (direction) and identify interaction with distance and the patient's etiology. The sensitivity of communication rate to different arrangements of the alphabet for the subjects whose data have been collected is currently being examined.

A computer-based technique for adaptive design using a search algorithm known as a reproductive plan (modelled after genetic evolution) is currently being evaluated for its applicability to the capabilities and needs of the user.

Voice Control for Disabled Children

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Sponsor: Rehabilitation Engineering Department, Regency Park Centre for the Young Disabled

Purpose — Voice input is an emerging technology that will allow a vocal but physically limited person to operate a computer. A recent survey at this center indicated that there is a small but significant need for voice-recognition communication systems. The aims of this project are: 1) develop software to enable disabled school children to use voice input instead of a keyboard to access the Apple IIe computer; and 2) develop software to enable speech pathologists to train improved articulatory discrimination in speech impaired children.

Progress — In the preliminary phase the speed and accuracy of the Apple Voice Input Module (AVIM) voice recognition system will be tested for children with cerebral palsy and muscular dystrophy.

The experimental phase will develop a series of command programs for accessing and using the AVIM. Application programs to improve articulatory discrimination in speech impaired children will be developed.

During the concluding phase, results of this project will be published in a professional scientific journal. The programs developed in the project will be made available for purchase.

Computer-Aided Assessment for Communication Rate Prediction

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Sponsor: National Institute of Neurological and Communicative Disorders and Stroke, MIT Undergraduate Research Opportunities Program, and Tufts University School of Medicine

Purpose — A significant proportion of severely speech impaired people, of various etiologies, have a primarily if not uniquely *motor* obstacle to their use of language. In response to this need, many techniques and devices have been developed over the past 10 years to provide speech-disabled people with alternative means for communicating their messages.

Progress — Part of a system being developed for computer-aided prescription of communication devices for the motorically non-vocal is the use of an instrumented motor assessment in which movement times are recorded during reciprocal tapping tasks. A patient's data are used as the basis of a closed-form model of time vs. distance, target size and direction. This model is then used to derive computer-estimated predictions of communication rate with candidate devices. Experimental data from eight disabled device users show strong correlations between predicted and actual time/character.

The assessment instrument is based on a lap-sized portable computer. An input interface for up to eight capacitive or mechanical switch lines has been built in an attached enclosure. A two-foot square test panel provides an array of holes which serve to locate pairs of targets and couple them to the interface circuit.

F. Environmental Control Systems for the Severely Disabled

[See also pgs. 130, 134, 289]

Investigation of the Utilization of a Robotic Arm by Disabled Persons in the Workplace

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Sponsor: Wichita Rehabilitation Engineering Center

Purpose — Persons who have disabilities that limit arm and hand functions cannot perform the manipulative tasks often required on the job. In recent years, robots of various design have been developed for use in industry. The researchers of this project feel that the robotic arm has potential as a manipulative tool that would allow physically disabled individuals to perform tasks at the workplace not possible before.

Progress — Two small robotic arms complete with microprocessors manufactured and marketed by Microbot, Inc. have been purchased and members of the staff have become familiar with the programming and function of the devices. The

robotic device in question is of the type that maintains a base position but has all of the motions the human arm is capable of performing.

One work station at Center Industries Corporation, Wichita, Kansas, has been developed in the Boeing tinning room for the purpose of utilizing one of these robots. The center employs disabled persons in a workforce integrated with able-bodied persons. The robot picks small electrical resistors having wire leads one at a time from a holding fixture, dips the wire leads in a liquid flex, then in molten solder, and then deposits the part in an alcohol bath. The worker is required to see that the next part to be manipulated is in place in the holding fixture by the time the robot is ready to pick it in the normal cycle time. The worker also observes the operation to ensure quality and to use a special tool for periodically skimming dross from the surface of the molten solder. The proper depth of molten solder is maintained by the worker dropping small beads of solder into the pot when it is deemed necessary for the robot to achieve the proper depth of dip. Using the teach pendant, the programmer manually operates the robot through the positions required in the cycle of operation. The microprocessor remembers the steps in the cycle and repeats the cycle automatically when asked to do so by the operator.

A worker who is quadriplegic from cerebral palsy has operated this work station with success by sliding a single part on a slightly elevated platform to a receiving slot in the platform. Below the slot is a slide chute, the bottom of which is the holding fixture, or holding device, from which the robot picks the part.

After picking the part, the robot then moves to immerse the wire lead of the part in the liquid flux and then to the molten solder which is contained in an electrically heated pot. The part is then turned end-for-end and the dipping process is repeated prior to depositing the finished part in the alcohol bath.

Long-Term Health Care Applications for Robotic Technology

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — An applications research team was formed to find areas in which robot technology would fulfill a need. The objectives of this study were three-fold. First, we wanted to identify tasks that were amenable to augmentation or replacement by robotic technology. Second, we wanted to survey the attitudes of the administration and staff toward computers and robots. Third, we wanted to see if our training techniques for the VA/Stanford University (SU) Robotic Aid could be used successfully by older users and to see how their performance compared to younger users. Observations were carried out in the VA Nursing Home Care Unit (NHCU) in Menlo Park, California. The team was composed of an interdisciplinary group of fifteen individuals with 25 years collective experience using the VA/SU robot, including neuropsychologists, physicians, nurses, engineers, health services researchers, medical anthropologists, education specialists, and spinal cord injured veterans. Researchers silently and interactively observed activity in the NHCU during various shifts over a one-week period. NHCU staff also contributed their ideas for applications of robot technology.

Progress — In the area of robot applications, our team was able to identify 12 major categories with 54 sub-groups. The major categories for these tasks are

transfer-lift-transport, surveillance, housekeeping, physician assistant, ambulation, nurse assistant, physical therapy, patient assistant, depuddler (urine cleaner), and mental stimulation.

The second stage of our research examined, by questionnaire, attitudes of staff and administration in the VA NHCU. The questionnaire contained 111 questions of different types: likert-style, open-ended, and dichotomous (yes/no), and semantic differential. It was administered to the NHCU staff as part of our standardized orientation.

Of our 22 respondents, three were male and 19 were female. Their average age was 45 years. Sixteen had nursing related staff titles and the remaining six had other health and human service professional staff titles. Highlights of their responses include:

None use a computer at work.

- 95 percent agreed with the statement, *Computers have made living easier.*
- 86 percent agreed with the statement, *A robot could be useful in my job.*
- 96 percent agreed with the statement, *Robots have many beneficial applications.*
- 100 percent agreed with the statement, *Robots can be used to serve people.*

The results of our research indicate a very positive response to computer/robot technology. In general, all respondents described robots as *positive, valuable,* and *useful.* The clinical group was very enthusiastic toward human service applications of robotic technology. Informal surveying and interviews with the patients who participated indicated unexpectedly positive responses.

Two in-patient residents and two staff members (a nurse supervisor and a social worker) were trained on the VA/SU robotic aid. The two patients were male: ages 62, and 90; the nurse supervisor was male, age 35; the social worker was female, age 39. Each successfully completed at least two sessions with the robot. All users were able to complete our first standardized training task (picking up a cup with straw and giving themselves a drink) within one standard deviation of our mean task completion time of two minutes. (Subsequent to our study, two more patients were trained: male, age 61, and female, age 87.) For the first time in history, the study established the feasibility of successfully training older persons in a long-term care facility to use a robotic aid.

Interactive Evaluation of Artificial Vision with Robotic Aids for Individuals with Disabilities

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Purpose — There is a need to introduce a vision capability to the robotic aid by easing the visual monitoring task for the user and providing more efficient assistance. The objective of this project is to study the feasibility of introducing a commercially available vision system into an interactive robotic aid for disabled individuals. In an unstructured environment, the artificial intelligence available to all present vision systems is far too low to allow useful machine perception. We propose to supply the missing intelligence by guidance from the user who is always present in the interactive system and by coding objects in a manner which is machine readable. The communications between the robotic vision system and

the human will be designed to allow the user to supervise operations by adjusting system parameters as needed, by supplying object identification for the vision system when necessary, and by confirming important vision system operations. Disabled persons who would use a system of this type have been active participants in the design of this project from the beginning. Their ideas and suggestions are incorporated in order to have continual feedback on the user requirements at all stages of the project (Interactive Evaluation). Several code types have been analyzed and a useful code, based on geometric shapes, has been identified.

Progress — A General Electric vision system has been connected to an IBM PC and loading between the GE and IBM systems, allowing greater total memory storage limited only by the available hard disc space of the IBM PC. Preliminary computer programs allowing interactive operation of the vision system with a disabled user have been written. At some future time, these users may be able to say to a robot, "Give me the glass," and the robotic aid will identify, grasp, and present the glass. We expect that adaptations of the use of a coded environment will allow mobile robots to contribute usefully in home, hospital, and nursing home environments, especially when simple carry and delivery tasks are involved.

Training Methodology and Results for a Voice-Controlled Robotic Aid

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Purpose — When we began our research in 1981 there were no established protocols for teaching individuals to use voice-controlled assistive devices such as a robotic aid. Within the Interactive Evaluation methodological framework for evaluating prototype assistive devices, training procedures have been developed, standardized, and researched for a voice-controlled robotic aid. Training is important to the prototype evaluation research process because it: 1) provides a mechanism for systematic collection of user feedback; 2) allows researchers to incorporate user input into design and development; and 3) is critical to acceptance of any advanced assistive device—particularly computerized, interactive devices, such as a robotic aid.

While we have trained users from age five to age 90, our approach is based on andragogical and pedagogical principles. Key concepts include: self-directedness, learning readiness, immediate applicability, and problem-centered learning tasks. User training on this system is accomplished in five sessions which are one to two hours in length. During each session, the user reviews existing expertise, acquires new information, practices the lessons in both structured and unstructured manners, and finishes the session with a task that helps the user assimilate the entire lesson.

Progress — Over 125 users have been trained to use the VA/Stanford University Robotic Aid. A 200-page user's manual (containing both self-paced and trainer-paced instruction) has been developed and utilized by people with widely varied educational backgrounds. These educational levels range from less than a high

school degree to Ph.D.s, both technical and non-technical, and M.D.s. Feasibility of training a wide age, educational, and ability range has been shown.

Tasks for the robotic aid have been defined and studied in the following areas: *personal tasks* such as activities of daily living (ADL) including cooking, serving, salt shaking; *recreational tasks* such as board games and painting; *vocational tasks* such as opening file drawers, extracting files, and presenting them; and *therapeutic tasks* to improve visual monitoring skills and range of motion therapy.

Proficiency levels for robotic use have been established based upon these task areas. All users learned to pick up a cup within one hour of their first introduction to the robotic aid system. Drinking, feeding, serving, cooking, picking up and placing and fetching tasks for a robotic aid were named by 90 percent of the quadriplegic respondents.

Development of standardized training procedures for instructing trainers is currently underway. A 'peer training' program also is being developed to match user and trainer according to age or personal rehabilitation experience. Future studies are designed to assess our ability to optimize successful use of the robotic aid by matching a particular training style with a particular set of user characteristics.

A Formulation of the Interactive Evaluation Model

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Purpose — The development of highly technical devices for disabled users requires continual feedback from the potential users to the project team designing the assistive device in order to assure that a useful product will result. This necessity for user input is the basis for the Interactive Evaluation Model. The Interactive Evaluation Model holds promise for minimizing project costs by introducing user feedback to increase the growth rate toward success of the project. In view of this fact, some quantitative formulation of the Model is necessary both to allow tests of this approach and to estimate the possible savings introduced by it.

The objective of this project is the mathematical formulation of the Interactive Evaluation Model. The formulation must account for user interaction within a team possessing the diverse expertise needed to research, design, and develop a highly technical assistive device. The aims of the formulation are to allow testable predictions of the model, to prompt specific questions that may refine the model, to identify data necessary to test the model, and to allow project design offering the highest probability of project success at minimum cost.

Progress — The mathematical formulation has lead to a simple set of equations giving the optimum number of class participants, including users, for a given project. The overall project costs can then be determined. In the simplest case the formulation determines that the optimum participation of a class of individuals should vary as the ratio of the class exponent to the class cost rate. Methods have been devised for estimating the class exponents and an illustrative example has been worked out based on our experience with medical care assistive aids. A

hypothetical project that operates at 230,000 dollars salary/yr without users can operate a 150,000 dollars salary/yr if potential users are included and provided the assumptions stated above are correct. We are now devising simple methods to test the validity of the Model and its formulation.

The results of this work can have deep significance in funding rehabilitation projects. The formulation of the Interactive Evaluation Model gives a prescription for designing a project to obtain success at a minimum cost by introducing users throughout the project life cycle. In addition, the formulation yields an outline for validating the Model. Should the Model prove correct, it offers a means for using monies available for publicly funded rehabilitaton projects as efficiently as possible.

Factors in the Design and Development of an Interactive Human-Robot Workstation

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Purpose — The Veterans Administration/Stanford University Robotic Aid is presently undergoing second generation development. The VA Merit Review Grant through which the project is funded, mandates design and development of the user interface where key specifications are based on the experiences of, and needs expressed by, the users of the first generation system. In the design of the interface to the robotic aid, the system designers must strive to maintain the relationship between the human and the robot while addressing human factors issues such as anthropometrics, task-related human factors, and value-related human factors.

An important subsystem of the human-robot interface is the user workstation; it is the physical component that links the user to the machine. General design parameters for a workstation include ergonomics, the functional requirements of the user, accessibility, aesthetics, safety, materials, integration into the user's environment, and connection to other systems. This particular system requires that the workstation: provide maximum access to the greatest number of users, both those with disabilities and the able-bodied; meet the needs of the technical development and clinical evaluation teams; and allow for multi-user interaction and easy group demonstration. The goal is a workstation that contributes to the overall effectiveness of the robotic aid through appropriate design and attention to interactiveness, accessibility, and autonomy (the degree of user control).

Progress — The first generation robotic aid served as proof of the concept that microprocessor-controlled human-scale industrial robots can be used by persons with physical disabilities in completing manipulation tasks. The objective of second generation development is to demonstrate the utility of a human-service robotic aid and to deliver the technology needed to make robotic manipulation aids broadly useful. Evaluation and testing of the robotic aid with disabled users has been performed according to the Interactive Evaluation Model. Over 90 people, 23 of whom are spinal cord injured, have been trained to use the first generation system in the past two years. User-specific training has focused on activities of daily living, recreational and vocational tasks such as preparing a meal, playing board games, and opening a file drawer to retrieve a file.

The clinical system employs voice as the primary input and output channel. Other input devices include a teachbox and a standard keyboard for use by the system operator in programming motion sequences, and a pushbutton for emergency stops. The sensory capability of the clinical system is limited to a few touch-activated microswitches located in the gripper. The second generation lab system includes: improved speech synthesis and recognition units; VIDOF for six-axis control of the robotic aid; the Ultrasonic Head Control Unit for two-axis control of the mobile base and the graphics screen cursor; a series of programmable switches to be dedicated as needed; a keyboard; and, a television camera to provide real time environmental information. A high resolution graphics display will be used, in addition to a diagnostic display and a video monitor, to enhance the presentation of system states to the user. The sensing capabilities of the robotic aid will greatly increase in the second generation, lessening the control burden on the user while increasing the utility of the robotic aid as new tasks can be attempted.

The design of this workstation has been likened to the design of a vehicle dashboard. Both require that special attention be given to the forward visual field of the driver or operator while maintaining the visual field of display, to hand (or mouthstick) reach for control action, and to knee and leg (or wheelchair) clearance for accessibility and comfort.

Future Plans — Iteration and refinement of design concepts are expected. The initial prototype, under construction now, will be used with the laboratory system. Following system debugging and further development, the updated robotic system, mobile base and workstation will be transferred to the clinical group for evaluation and user trials. This cycle of development and evaluation will continue until the delivery of what will hopefully be deemed a practical human service robotic device with an appropriate human-machine interface.

Design of Bathrooms, Bathing Fixtures, and Controls for Disabled and Elderly Persons

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Purpose — The objective of this research is to complete the development of four bathing fixtures designed by the investigators. Each of the fixture designs is to be evaluated through usage by disabled and elderly subjects, modified as necessary to meet usage and production criteria, and finalized for manufacturing. The four fixtures under development are: a cushioned shower (with vinyl skinned padded surfaces); a shower with two seats; a roll-in stall shower with a wall mounted seat; and a two-piece roll-in shower.

Each shower design responds to the physical characteristics of certain types of disabilities. For example, the cushioned shower has a padded surface to reduce the tendency for skin breakdown and a contoured seat area to provide trunk stability; the shower with two seats is designed for use by right or left hemiplegics or by individuals who require assistance during bathing; the roll-in shower with a wall seat is designed for use by persons who can transfer from a wheelchair or by persons who enter the shower in a standing position; and the two-piece roll-in shower is designed for use by persons who use a shower type wheelchair rather than a shower seat.

Progress — Evaluation and design methodologies are being used in this project. The evaluation of the four fixtures has been completed. This was based on quantitative and qualitative analysis of user performance, user safety, and accomplishment of bathing tasks. Task accomplishment was measured by success or failure of tasks overall user performance, time-motion studies, and user safety as determined by behavioral observation. User satisfaction was determined from a post-trial interview. The pending design modifications are based on the results of the fixture evaluations.

The evaluation of the shower fixtures was conducted through observation of forty-four disabled subjects taking showers. For each subject tested, a pre-trial questionnaire was filled out that documented current bathing habits, including safety, frequency, and method of bathing. Each subject was given instructions verbally and through an illustrated brochure that showed how to use each fixutre. All fixture trials were videotaped for later analysis of movement. Subjects used only the fixtures that could (in the opinion of the research team and the occupational therapist) safely accommodate their physical capabilities. Following the use of each fixture a post-trial interview was administered to determine the subject's perception of the fixture in terms of safety, comfort, ease of use, and overall acceptability. Perceptions were recorded by the occupational therapist using a five-point scale.

Analysis of the visual and coded data was done through frequency studies and the determination of means and standard deviations. Visual data from the video tapes were translated to coded data for analysis. Transfer, bathing, and exiting tasks were analyzed both to determine success/failure and to document any hazardous movements or conditions.

Preliminary Results — The evaluation indicates that the four fixture designs as a group can safely accommodate a wide variety of physical disabilities. Of the three fixtures that are usable by persons capable of wheelchair transfers, the roll-in shower with wall mounted seat was used by the most number of subjects. Subjects with limited range of motion in the lower extremities often had difficulty using the cushioned shower largely because in the final bathing position the feet were elevated. For most subjects the seating positions of the roll-in shower with seat and the two seat shower were preferred to the seating position of the cushioned shower. The two-piece roll-in shower was slightly undersized for some subjects causing problems in closing the shower curtain.

Findings of the evaluation are now being used to redesign each of the four designs. The two-piece roll-in shower is being lengthened to better accommodate a tall wheelchair user and the floor of the fixture is being modified to accept a new grating design. The cushioned shower will be modified so that the foot rest area is not as high off the floor and the grab bar location and design is being changed. Cushioning will be applied to the wall mounted seat to better accommodate persons with loss of sensation. The two seat shower is not expected to be modified at this time.

Future Plans — Following the modification of each of the three showers, the new prototypes will undergo a limited evaluation. Following this testing the completed shower designs will be available for marketing.

Ultrasonic Head Control Interface (UHCI)

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Purpose — Successful development of a device that can overcome current interface shortcomings would be of significant value to severely injured individuals who wish to control their mobility or communication in a socially acceptable and aesthetically pleasing manner. In particular, the existence of a device that operates at a distance without the necessity of mechanical contact, uses a control site not required for sensory input, and is easy to learn and use would be an ideal solution. Other features such as modular construction, low cost, the ability to accommodate many users, and self calibration would contribute to the universality of the interface, and thereby stimulate its widespread use.

Ultrasonic distance ranging requires no physical contact with the object of interest. Used as an interface, a user would not feel 'wired-up' with a device incorporating this technology. The investigator hypothesizes that an array of distance ranging sensors can monitor the head position of a severely disabled quadriplegic operator to obtain command and control information for the operation of mobility and communication devices.

Progress — In this project, two Polaroid ultrasonic distance ranging sensors are employed. They emit inaudible sound waves that propagate through the air until reflected by an object. A portion of the echo signal returns to the transmitting sensor and is detected by the associated electronics. The measured time from transmission to the reception of the echo is proportional to twice the distance from the sensor to the object. In this rehabilitation application, two separated sensors are directed at the user's head. The two distance ranges, one from each sensor to the head, and the fixed separation of the sensors describe a triangle whose vertices are the two stationary sensors and the user's moving head. A geometric relationship allows the offset from the base line and center line of the two sensors to be calculated. This information is then used to map the user's head position onto a two-dimensional control space.

In operation, users of the Ultrasonic Head Control Interface (UHCI) merely tilt their head off the vertical axis in the forward/backward or left/right directions. Their head position can produce the same effects as a joystick. Both can be used to control devices to which they are attached such as a wheelchair, a communication aid, or a video game.

The main advantage of this type of interface is that no mechanical contact between the sensors and user's head is required. This effectively separates the user from the device being controlled. Users should not feel confined by devices around their face or body with this unit, as frequently occurs with other interfaces. The use of the remote sensing ability of the UHCI should result in rehabilitaton devices that are socially acceptable and cosmetically pleasing.

Preliminary Results — UHCI have been installed on two electric wheelchairs. The first is an E&J Model 3P equipped with a reclining Recaro seat and is in use in France by a quadriplegic woman. The second is mounted on an Invacare Roll IV with a Solo Products Power Pack and is being evaluated by spinal cord injury patients at the VA facility. Both units have been operational since June, 1983. User evaluation has been performed with ten quadriplegic individuals. After a short

demonstration and training session, they were transferred into the chair and most were able to successfully navigate the chair without problem. Users state that they preferred the ultrasonic head control to the chin-controlled joystick wheelchairs.

A generalized interface for a robotics application also has been developed. With the UHCI, the robot user will be able to select tasks and control the operation of a mobile mechanical arm. Specifically, the path for the vehicle will be specified by 'drawing' its planned trajectory on a CRT with head motions.

Future Plans — Another robotic application of the UHCI is being pursued. Used in conjunction with a robotic arm, it will provide control of its hand position. The user's head position will be used to control two degrees of robotic arm freedom. Compared to the current voice recognition method, a faster and more interactive manipulation of the hand is anticipated.

In a communications application, the UHCI will monitor the user's head position and control a moving light cursor in an X-Y matrix of letters and words. Selection is then accomplished by pausing on the desired square. A commercial joystick-operated aid has been donated for this work.

A technical manual documenting the work on the UHCI, including background material, electronic schematics, computer program listings, explanations, and illustrations has been compiled. Its intended purpose is to provide information that would allow a technically knowledgeable and adequately equipped person to construct a UHCI and apply it to the control of devices such as powered wheelchairs. This manual has been made available to over 40 interested parties, who are considering the UHCI for research or commercialization.

Within the VA, a Request for Evaluation has been submitted and approved. Funds will be made available for the commercial production of four units which then will be evaluated at VA medical centers throughout the country. A decision will then be forthcoming regarding the desirability of purchasing additional electric wheelchairs using the UHCI for disabled veterans.

Development of Environmental Control Units for Disabled Veterans

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Purpose — A large population of elderly veterans and civilian population are confined to a single room, such as an extended care hospital or nursing homes. Many people in this situation need help in simple tasks such as operating lights, TVs, radios, beds, and other appliances. An environmental control would allow them to perform these tasks themselves rather than having to call for assistance.

The Electronic Industries Association (EIA) has a task group developing standards allowing remote control of lights and appliances within a room for the able-bodied. If these standards are implemented, this would allow equipment from different manufacturers to work together.

Progress — This project will research the desirability from both a technical and economic viewpoint of using these emerging specifications in an extended care facility. If these components can be used, system cost can be minimized because only a controller, usable by the handicapped, would need to be designed.

The Development of Environmental Control Systems for the Severely Physically Disabled

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Sponsor: Scientific and Research Trust of Central Remedial Clinic

Purpose — Severely physically disabled children and adults can control their own environment by the application and adaptation of technological development, providing they can reliably operate a single switch. In this way, they can be more truly independent.

Recent developments (especially in the United States) have shown that microcomputers can be used as controllers to send switching signals to slave devices through the in-house main wiring. This removes the need for hardwired interconnections. To date, these systems have, in the main, been developed for use in conjunction with American electricity supply standards and Bell telephone switching protocol. As yet, little or no work has been done on developing similar systems for use in Europe. By making the relevant hardware and switching modification, this project will develop showcase systems for use in Europe, in addition to developing special systems to suit individual needs. It is expected that these systems will have universal applicability throughout Europe.

Reinforcement of Voluntary Head Control

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Purpose — Nonambulatory patients with hypotonic neck and head muscles are subject to additional complications because of their limited field of vision, feeding, speech, and other difficulties.

Progress — This project intended to improve the strength of the head and neck muscles by using a music biofeedback device. A mercury switch attached to a hat was designed to trigger music in earphones worn by the patient as soon as his head reached within 30 degrees of vertical. Once the music of choice of each of four patients was determined, half-hour sessions on a daily basis were conducted for two weeks. Preliminary data show that the total time the head was within 30 degrees of vertical improved by an average of 57 percent at the end of two weeks, with substantial carry-over improvement for other activities during the day.

Voice-Operated Appliance Control

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Purpose — Recent advances in voice recognition technology have provided low-cost integrated circuits capable of speaker-independent recognition of up to 16 words. This center has developed two devices to demonstrate the usefulness of this technology to disabled people.

Progress — One device is called the voice-operated appliance control (VOAC). The VOAC allows its user to operate up to 256 electrical devices with three simple voice commands: "go ahead," "search" and "stop." "Search" causes the

VOAC to sequentially display its three basic control modes: "all on," "all off," and "select." When the desired mode is displayed, it is selected by saying "stop." The user executes the mode by saying "go ahead." Selecting "all off" or "all on" will turn all units off or on. Selecting "select" allows control of individual units. "Faster" and "slower" control the display rate at all times.

In the select mode, the VOAC sequentially displays the numbers of available units. A unit is selected by stopping the display when the unit's number appears. When the unit has been selected, the VOAC sequentially displays functions available for that unit. Possible functions are "on," "off," "bright," "dim," and "momentary." The latter will turn a unit on until the user says "stop." As before, functions are selected by stopping the display and saying "go ahead."

Training Capuchin Monkeys to Serve as Aides for High Level Quadriplegics

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — This project is an ongoing attempt to refine the procedures by which capuchin monkeys are trained to serve as aides for high level quadriplegics.

Progress — Work is underway to meet the following objectives:

1) Approximately three-fourths of the training procedures used in teaching a basic repertoire of skills have been standardized and described in a 100-page illustrated training manual as well as instructional videotapes.

2) A solid food dispenser designed to replace a liquid reward dispenser underwent field testing in the Fall of 1985.

3) Seven high level quadriplegics are now using simian aides. One cerebral palsy patient was paired with a simian aide in the Fall of 1985.

4) A breeding colony was established in 1985 at the Mannheimer Primatological Foundation in Florida to produce 20 to 40 infant Cebus per year. A breeding colony also has been located in Argentina and 16 female infants were purchased during the Fall of 1985.

6) A non-profit organization has been established to apply the knowledge gained from the simian aide research. Financial support for the organization has been secured via a corporate sponsor and as mature animals become available, placements of simian aides will begin at a rate of 20 to 40 per year in 1987.

7) An evaluation of the simian aide research is currently being conducted by the evaluation unit of the Department of Rehabilitation Research and Development. A second evaluation by the New York University Spinal Cord Injury Research Unit is planned for January of 1986.

8) A market survey testing the preferences of high level quadriplegics for simian aides versus robotic arm work tables was scheduled for the Fall of 1985.

9) An experimental program for teaching college students how to train monkeys was initiated in September of 1985. Efficiency and cost-effectiveness will be evaluated over the next two years.

10) Canada, Argentina, and Israel are now beginning their own simian aide programs; training material and primate selection information is being provided to them at no charge.

Wheelchair Control and Robot Arm/Work Table System for High Spinal Cord Injured Persons

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Purpose — The objective of the project during this period (June 1984 through March 1985) has been the completion of an important phase of clinical evaluation of the Robot Arm/Work Table System at the Spinal Cord Injury Services at the VA Medical Centers in Richmond, Virginia and Cleveland, Ohio. In parallel with this testing, two important engineering improvements were made to the system. Development of a new, self-adjusting chin controller of the wheelchair was completed, and three axis simultaneous motion capability of the Robot Arm was achieved. Details of over two years of clinical testing were given in the technical article in the January 1985 Volume of the Journal of Rehabilitation Research and Development.

That report includes the experiences of users who evaluated the equipment during the first six months of the current report period, as well as those of users who evaluated the equipment during the previous year and a half. The current report summarizes those results and the results of an additional user who evaluated the equipment during the remaining months of the current report period.

Progress — Through December 1984, 20 male quadriplegics between 21 and 60 years of age at evaluation had been involved in the evaluation in three geographical areas, i.e., Baltimore-Washington, Richmond, and Cleveland. They ranged from five to 26 years between time of injury and evaluation. The levels of injury ranged from C-2 to C-5. Individual accumulations of time actually working with the equipment ranged from one hour to over 100 hours; 316 meals were eaten by these individuals using the Robot Arm. Among the nine quadriplegics who tested the equipment at the Richmond VAMC, seven indicated that they found the equipment gratifying to use, especially for self-feeding. Among the seven quadriplegics who tested the system at the Cleveland VAMC, none found the system useful. They cited a number of reasons. Regardless of the differences in overall assessments, agreement existed on two general problems.

One problem was lack of adequate adjustability of the wheelchair chin controller to enable the operator to compensate for changes in his posture in the wheelchair. This accounted for a degree of incompatability of the system with reclining users. There were also reliability and maintenance problems with the original design. The second problem was slowness of the Robot Arm in accomplishing repetitive tasks such as self-feeding. Both of these problems were addressed and engineering design changes were made to the hardware.

A new chin controller was designed to interface with the E&J Model 3P wheelchair. This design change addressed problems such as the lack of ruggedness, too much head motion required, lack of provisions for readjustment by the user, and too troublesome for attendants to mount and align on the wheelchair frame. In order to speed up the cycle time of the Robot Arm, a new multiaxial controller was designed based on the use of the 6809 microprocessor. The 6809 microprocessor and its associated software allow additional flexibility for programming task trajectories and give the system greater operational reliability.

The user who evaluated the equipment during the final months of the current report period was a 27-year-old C3-5 quadriplegic with a motor residual of partial function of the deltoids, one pectoralis major, and one biceps. With the exception of the new multiaxial capability, he evaluated the Robot Arm/Work Table with all subsystems including an electric wheelchair with the new chin controller. He worked with the equipment over a three-month-period in the OT facility at the Richmond VAMC. He ate 24 complete meals with the Robot Arm. He had very positive comments about all aspects of the system and specifically about the new wheelchair chin controller's responsiveness and self-adjustability.

Future Plans — Clinical evaluation of the new simultaneous multiaxial motion feature for the Robot Arm is anticipated during the next report period.

G. Wheelchairs, Including Seating and Controls

[See also pgs. 110, 130, 147]

The Sunburst Tandem

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Individuals with various physical disabilities resulting from paraplegia, low level and incomplete quadriplegia, amputation, muscular dystrophy, multiple sclerosis, stroke, cerebral palsy, blindness, etc., who endeavor to live healthy and meaningful lives may benefit greatly in their physical, psychological, and social well-being from participation in recreational activities with family and friends. With the development and subsequent availability of an appropriate design, tandem bicycling is one highly integrative activity which will promote participation by individuals with disability.

A tandem bicycle to be shared by individuals with and without disability will literally provide a vehicle for integrated mobility and recreation. On such a tandem, many excluded from the revitalizing activity of bicycling will experience the freedom, exhilaration and accomplishment of riding a bicycle.

The pre-production development of a single rider arm-powered bicycle, the *Handbike*, is essentially complete. As a spin-off from the development of the *Handbike*, the first prototype of a tandem called the *Handbike Tandem* for disabled and able-bodied to share, was completed in June 1983. Conceptually, the configuration of the *Handbike Tandem* consists of merging the *Handbike* in the front with a standard bicycle in the back. In the interest of independence and equality, this first tandem prototype was designed to be ridden by one rider alone in the front or back position. The experience gained by the development of the *Handbike* and the *Handbike Tandem* has led directly to the design of the second tandem prototype called the *Sunburst*.

Progress — Although similar to the *Handbike Tandem* in rider configuration, an alternative drive system and vehicle identity was planned for the *Sunburst*, completed in June 1984. On the *Sunburst*, arm- and foot-powered recumbent cycling in the front combines with a standard bicycle in the back.

The back rider steers through a remote linkage from the handlebars to the front wheel, and pedals in a standard bicycling posture. The front rider sits in a recumbent position and powers with any combination of arms or legs. With the *Sunburst's* configuration (as opposed to a standard tandem), both riders have a clear view ahead and find it easy to converse. The back rider controls the rear caliper brake with a hand lever. In addition, both riders activate the front hub brake by backpedaling.

The *Sunburst* riders move as one, combining their pedaling effort and balance to their best ability. The front cranks directly couple allowing the front rider to assist or passively exercise his or her own less functional limbs. For those who prefer not to either actively or passively move their legs, a leg rest attaches to the seat. A freewheeling system allows the front rider to stop pedaling and rest while the back rider continues to pedal. If a rider is unable to pedal at all, he or she may just go along for the ride. When the *Sunburst* comes to a stop, the front rider can lower a secure kickstand. The front drive system and seat are detachable, yielding a single rider bicycle, when desired. The front seat also may be converted into a cargo area increasing the versatility of the *Sunburst*.

With the front position designed to appeal to able-bodied riders as well, an individual with disability has the dignity of riding the *Sunburst* in the same position as able-bodied friends. In addition, the visibility of the *Sunburst* in the community heightens public awareness by drawing attention to our common desire to be mobile and to participate in recreational activities, unmitigated by disability.

A design documentation manual is being assembled as a vehicle for technology transfer of the *Sunburst* to manufacturers. Further performance and mechanical evaluation is needed to help assure that the most worthy tandem product will be available to individuals with disability.

Optimal Biomechanical Design Development of Arm-Powered Mobility Vehicles

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Purpose — Individuals with lower limb disorders and spinal cord injuries are looking for better devices to enhance their mobility and through it the quality and degree of independence and societal integration to which they are entitled. As far as arm-powered vehicles are concerned, few alternatives to the wheelchair-handrim device are currently available and precious little research effort has been made to fine-tune the rider to his mobility aid. A need exists, therefore, to better understand the operator-vehicle interface in order to design better arm-powered vehicles that are ergonomically attractive, economically feasible, and help to optimize the biomechanical efficiency of the arm-cranking tasks.

If we are to optimize arm-powered vehicles we must conduct research that develops the best vehicular drive mechanism that successfully incorporates neurophysiology and biomechanical control of the upper limb as it interfaces to a given drive mechanism. Only then will the tens of thousands of disabled individuals be afforded the opportunity to have maximum utilization of their mobility access.

Progress — Modern control theory and, in particular, optimal control theory, have been used successfully for decades by the aerospace and military communities as important engineering tools for the development of advanced designs which optimize device performance. Advanced modeling efforts using digital computers have enabled engineers to explore design parameter changes quickly, without resorting to expensive prototype development and re-engineering. More recently, attempts have been made to apply these same optimization and modeling techniques to biological systems, in particular to open-link kinematic structures which propose to model human locomotion and jumping.

It is the major hypothesis of this proposed research that modern control theory, when coupled with careful human biomechanical performance measurements, can lead to nearly optimal arm-powered drives for use in mobility and recreational vehicles for the disabled. A tractable biomechanical model may then be developed for the upper limb as it applies to a broad spectrum of arm-cranking tasks. We can use this model to develop optimum design parameters for various arm-cranking mechanisms (e.g., rotary, eccentric, and linear drive schemes).

Pressure Sores, Blood Rheology, and the Mechanical Properties of Soft Connective Tissues

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Sponsor: Scottish Home and Health Department

Progress—

Pressure Sores. Work in pressure sores centers on the prevention of sores by the detection of patients at risk and the provision of specialized equipment. There is a major research program in the measurement of the mobility of elderly patients both in chairs and in beds. Mobility measurements are made by supporting the devices on low profile load cells; data conversion, logging and analysis are carried out by an on-line microcomputer. The initial work on bed mobility has been completed and has demonstrated useful and simple parameters for selecting those patients at risk of developing pressure sores. Work on patients in chairs is at an earlier stage.

Blood Rheology. There are studies of blood rheology and transcutaneous oxygen tension in patients with diabetes. The aim is to elucidate the connection between abnormal blood viscosity and red cell deformabilty in these patients and the tissue oxygenation status. Patients with poor and good diabetic control and quantified neuropathies will be investigated. Initial results have been obtained on the blood viscosity and red cell deformability and the major integrated program will be commencing imminently.

Work is also underway on the relationship between blood viscosity and red cell deformability and the outcome of patients who have suffered an acute stroke. Previous studies on the connection between hematocrit and outcome indicated that elderly patients with an abnormally low or abnormally high hematocrit did worse than patients within the normal range.

The Mechanical Properties of Soft Connective Tissues. There is a continuing research effort in the characterization of these tissues, with the emphasis being on skin.

Seating System for Patients with Multiple Spinal Deformities

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Purpose — Patients who are severely developmentally disabled exhibit scoliosis, pelvic rotation and obliquity, scissored legs, spasticity, and hyper-reflexia. After several years of experience, a systematic management program was developed incorporating a multidisciplinary approach. The management program consists of three phases: pre-surgical bracing, spinal surgery, and post-surgical bracing.

The role of pre-surgical bracing is to contain the deformity to manageable levels during the growing years so that once the deformity stabilizes it does not present a high-risk surgical case for the second phase. After spinal instrumentation with Luque technique, a different seating system is designed for the patient allowing him to stabilize in the desired posture.

Progress — Both pre- and post-surgical seating systems were designed with corrective rather than adaptive principles. They incorporate a maximum surface contact with the patient and contour to normal posture of same size. The backrest provides continuous contoured lateral support from below the axilla to the hip. The seat also has lateral supports to prevent rotation and a built-in abductor post to prevent lower extremity scissoring and to stabilize the pelvic anatomy. All padding material consists of Action Gel to provide pressure equalization. The seat and back braces are attached to a regular wheelchair frame with quick-disconnect latches to preserve portability and may be angulated relative to each other as may be necessary for the individual patient. Generally, hip and knee flexions of less than 90 degrees were found to provide substantial relief for hyper-reflexia (extensor thrust).

Wheelchair Seating Effectiveness and Wheelchair Performance

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Purpose — Many disabled children spend a large part of each day in an electric wheelchair. They need comfortable, supportive seating and a reliable wheelchair that meets their needs. The effectiveness of new seating systems has not been objectively assessed, and the reliability of electric wheelchairs needs to be improved.

Aims are: to develop assessment procedures for wheelchair seating systems in terms of cost, comfort, cosmesis and function, and to evaluate six new special seating systems using the protocol established; to conduct performance measurement studies on electric wheelchairs; and to use quantitative procedures to improve client/wheelchair matching, using the results from the above.

Progress — This study involves two concurrent streams of work, concerned with seating effectiveness and wheelchair performance.

During the preliminary phase, protocols will be developed for the comparison of alternative special seating systems. Several new seating systems, such as matrix supports and foam-in-place methods, have recently become available. Five each of six alternative seating systems will be purchased for fitting to groups of subjects matched as closely as possible for age, sex, diagnosis and degree of impairment.

In the experimental phase, 30 cerebral palsied children will be fitted with special seating systems and each will be evaluated over a three-month-period from the date of fitting.

In the concluding phase, the results of the evaluation, which will include prescription criteria, will be published in a professional scientific journal, and an instructional course on modern seating techniques for cerebral palsied children will be conducted.

In the preliminary phase, a protocol data measuring/logging system will be purchased, adapted and mounted on an electric wheelchair and an adjustable ramp will be built for testing the static and dynamic stability of wheelchairs.

In the experimental phase, the data logger will be used to analyze patterns of wheelchair usage, which will be related to problems experienced in wheelchair use.

During the concluding phase, the results of this study will be made available to the Standards Association of Australia and a professional scientific journal, and we will work with wheelchair manufacturers to improve the design of electric wheelchairs, control interfaces and wheelchair seating.

Many children with cerebral palsy spend a large part of each day seated in a wheelchair. Inappropriate seating is a major contributor to the problems they experience in balance and comfort. Widely accepted seating guidelines in cerebral palsy have not been scientifically validated.

The number of children at this center using electric wheelchairs has increased from two to 87 in the last nine years. There are, however, currently no standards or laboratories used in Australia for testing the performance of wheelchairs, and consequently the incidence of breakdowns is high. An internal report at the center indicates that annual maintenance costs on some makes are up to 30 percent of purchase price.

Preliminary Results — This project will result in improved seating for disabled children, at this center and elsewhere. It also will result in the establishment of an Australia-wide wheelchair testing facility at the Regency Park Centre for Young Disabled.

Development of Wheelchair Standards

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Purpose — This work is being carried out by contract with the Rehabilitation Engineering Society of North America (RESNA) with administrative assistance through the Director of Research, Paralyzed Veterans of America. The work has been in progress for several years but under this contract for the past year. Regular meetings of the full committee are held on a six-month basis plus international standards meetings and ad hoc committee meetings on special projects. The representatives of RESNA and the committee attend the international working group meetings working to establish the standards through the International Standards Organization (ISO).

Research and testing are carried out in the laboratories of the University of Virginia, University of Tennessee, Stanford University and Palo Alto VAMC, VA

Rehabilitation Engineering Center Laboratories and the Laboratories of Everest and Jennings and Rolls-Invacare.

Representation in the committee covers a broad spectrum of persons interested in wheelchair and wheelchair problems from the academic community to the manufacturers of wheelchairs and interested consumer groups, therapists from a number of Spinal Cord Injury Units and representatives of the Veterans Administration and the Food and Drug Administration.

Progress — Testing has been completed and the ISO accepted standards determination of static stability. Work has been completed and submitted to the International Standards Organization for: the determination of the efficiency of brakes; determination of energy consumption of electric wheelchairs; determination of overall dimensions, mass and turning space; determination of maximum speed, acceleration and retardation for electric wheelchairs; climatic tests for electric wheelchairs; determination of the obstacle climbing ability of electric wheelchairs; test dummies; and determination of the coefficient of friction of test surfaces. This committee has been a major contributor in the areas of the static testing, dynamic stability, maximum speed and acceleration, seating dimensions, static and impact fatigue testing, and determination of the coefficient of friction.

Items on which testing has not been completed, that is, the determination of dynamic stability of electric wheelchairs, determination of seating dimensions, static impact and fatigue strength for manual wheelchairs, and determination of tracking characteristics of wheelchairs, is well underway and it is anticipated that the work will be accomplished within the next eighteen months and that this will result in acceptance of standards that will be identical for ANSI and ISO.

Work is being done on the appropriate disclosure of the results of these testings and standards as would be applied to wheelchairs. The appropriate disclosure forms are being developed. It is anticipated that this will take the form of disclosures that will be of use to consumers and practitioners in comparing various wheelchairs to determine which would be the most appropriate for a given individual. The majority of these standards will be of a descriptive nature and not of a restrictive nature. It is expected that all the goals of this project will be easily completed within the remaining two years of the contract.

Developing Safety Standards for Wheelchair Occupants in Vehicles

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Sponsor: Department of Transport, Government of South Australia

Purpose — Testing of vehicle restraints for wheelchair occupants has revealed that commonly used methods are unsafe. Previous work at Regency Park Centre for Young Disabled led to the development of a crashworthy restraint system for wheelchair occupants and, more recently, the broader issue of safety standards has been addressed.

The use of effective restraints for wheelchair occupants in vehicles is hindered by several factors: some types of wheelchairs are clearly unsuitable for vehicle seating and very few wheelchairs have been designed for use in vehicles; the wide variety of wheelchairs in use complicates the design of restraints; vehicles do not have suitable anchor points for wheelchair occupant restraints; there are no

accepted standards for wheelchair occupant restraints; and no information or advice is available to prospective users or buyers of wheelchair occupant restraints.

Progress — The following initiatives are being developed to overcome these difficulties: an illustrated booklet to inform prospective users and buyers of the need for restraints, the choice of suitable wheelchairs, and related safety issues; an informative videotape, similar to the booklet in content; a comprehensive set of design and performance requirements for wheelchair occupant restraints; a code of practice, to be implemented in South Australia, establishing a scheme to ensure that restraints satisfy those requirements, are correctly installed, and that vehicles are adequately reinforced; and an Australian standard for wheelchair and occupant restraints is in preparation. These developments will provide protection for wheelchair occupants travelling in vehicles and facilitate transport of severely disabled people.

Skin Blood Flow Under External Loading

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Although it is generally accepted that alterations in skin blood flow are associated with the onset and development of pressure sores, demonstrations of that association are nonexistent. The question is "Does skin blood flow response to external loading differ in patients who develop pressure sores from that of patients who do not?" If such differences do exist and can be easily measured, then patients might be assessed upon hospital admission with regard to pressure sore risk, so that appropriate precautions may be initiated as necessary.

Progress — In order to ensure the measurement and proper grouping of each of the important parameters, a dimensional analysis was performed which indicated that the change in skin blood flow under an external load applied over a bone could be represented mathematically.

Early experimental work has been focused on gaining experience with the laser doppler instrument and its limitations. It was found that applicaton of external loads to the skin caused a decrease in DC level of the instrument, which in turn produced an artificial decrease in indicated flow level. The instrument was subsequently modified to prevent this effect.

Preliminary experiments have been carried out on several able-bodied and spinal cord injured subjects with the subject in a side-lying position with known weights applied to load the skin over the proximal femur by means of a cylindrical fixture which houses the laser doppler probe. Blood flow occlusion was not seen even at extremely high external loadings. Additional investigation indicates that the laser doppler does indeed indicate zero flow if all motion ceases, which does not necessarily occur when net blood flow decreases to zero. Therefore, the problem we now face is that of determining the nature of the motion that is being detected by the laser doppler at high applied pressures.

Both cylindrical and spherical indentors have been machined which house the doppler probe with a flush surface to the skin and also permit direct application of

the loading weights to a built-in flat platform. Skin displacement is measured by marking the shaft of the load applicator for each applied load.

Preliminary Results — Results to date show a decrease of skin blood flow with applied loading in all cases, but do not indicate skin blood flow occlusion even at high pressure loadings. We are investigating the source of this residual signal, which we believe indicates some type of motion other than blood flow since all vessels should be occluded at these levels. The indicated residual motion could be tissue creep, fluid leakage, or other cellular motions, and will be investigated using either animal or simulation models. In addition, we are preparing to compare the output of our instrument with that of a laser doppler instrument from another manufacturer since the signal processing of the two units is somewhat different. These comparisons will be performed on human subjects using the protocol described above.

Skin displacement measurements are unaffected by the above instrument characteristics and have yielded findings which indicate that the tissues overlying the proximal femur become stiffer with age (higher pressure required for the same displacement), regardless of spinal cord injury. The tissue characteristics are found in all cases to be nonlinear, becoming stiffer with increased loading.

Future Plans — Systematic testing of able-bodied and spinal cord injured subjects in the four groups specified above is planned as soon as the proper correction of the doppler flow data can be established. It is planned to test correlations between skin blood flow response to pressure and shear loadings and the occurrence of pressure sores in each of the four groups to be studied.

Seat Cushions for the Paralyzed

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Pressure sores continue to be a problem area for spinal cord injury and geriatric patients. The role of shear forces developed in sitting with respect to trauma in the region of the ischial tuberosities may be significant in pressure sore causation. Prior results have shown that cutaneous pulsatile flow within the buttocks of seated paraplegic subjects is considerably smaller in magnitude than that of normal subjects. It also has been shown that the sitting shear force developed by paraplegics is considerably larger than corresponding measurements of normal subjects. At issue is the relationships, if any, between these factors; what role does shear force play in producing ischemia in those who are paralyzed?

A second goal is the development of a clinical device capable of monitoring cutaneous blood flow at the patient support surface interface. Such a device is to be compatible with cushions, mattresses, etc.

Progress — A hard seat equipped with instruments measuring pressure, shear and cutaneous pulsatile blood flow was augmented with computer devices yielding a harmonic analysis of plethysmographic waveform. By comparing ratios of harmonic intensity (2nd and 3rd) to that of the fundamental vasoconstrictive

tendencies are perceived and measured. To date, 18 normals and nine paraplegics have been tested. Sought is that degree of arteriolar blood flow inhibition, if any, arising through shear and paralysis.

A prototype fiber optic sensor of cutaneous blood flow has been completed and tested. Offering little thickness and considerable flexibility, such a device might be employed to determine those patients prone to cutaneous blood flow occlusion at unusually low seating pressures. Cushion evaluation is also a prospective use.

The current prototype, when tested against a conventional mercury strain gauge sensor, reveals deficiencies in the depiction of waveshape contour. Specifically, differences exist in rise time (acceleration) and dicrotic notch portrayal. Electronic filter and photo sensing devices contained within the fiber optic system are undergoing modification.

Wheelchair Usage Monitor

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Sponsor: Veterans Administration

Progress — Actual work has been in progress for six months. At this point, the basic device has been fabricated and completed, including the internal software to record and store the data. In addition, the interface device that would transmit this data to an appropriately configured computer for further analysis and storage has been completed.

The only remaining item to be completed for this project is the development of an appropriate acceleration sensor that is compatible to the device and the basic objectives of the project, i.e., a small device that can be easily attached to any wheelchair and can accurately record usage data. It is anticipated that this work will be completed within a very short time and the devices will be ready for testing.

Alternate Transit Vehicle for the Physically Disabled Person

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Sponsor: VA Rehabilitation Research
and Development Service

Purpose — The objective of this research is to design systems and subsystems for an alternate to present powered wheelchairs.

Progress — This project began as a graduate feasibility study examining conceptual designs of a transit vehicle for physically disabled persons. It became apparent that the major obstacle to any conceptual design was the fact that the control electronics did not exist. In addition, semi-structured interviews with powered wheelchair users revealed possibilities for improvement in present wheelchair controllers. The logical direction for this project then became to examine the electronics of wheelchair control, with a goal of designing a controller that was flexible enough to serve as a retrofit item for present chairs or the more sophisticated control of future conceptual designs.

The first prototype has been constructed and is undergoing initial field-testing. The controller is microprocessor-based with optical encoder feedback and is an

original design in power processing. As a retrofit item for present powered wheelchairs, it offers several advantages in addition to a projected consumer cost that is below that of present controllers. One advantage is that costly hardware modifications which customize the controller to special needs are not needed because the design is implemented in software instead of hardware. All controller characteristics are set in software and are user/therapist programmable. The controller is silent in operation with no audible relay chatter or motor hum. Closed-loop control provides the classical advantages in addition to a path memory feature that allows the chair to automatically back out of a confined area along the same path it entered. A degree of self-diagnostics is presently functional and is presented to the user through an 8-character display. The processing power of the controller remains virtually untapped with much of the signal processing handled by support devices. This allows the controller to assume additional functions in addition to driving the wheelchair.

Future Plans — With the basic hardware design finalized, future work will be concentrated in software development. Two grant applications are currently under consideration for funding. They address the human factors considerations of wheelchair control. Control strategies to be examined include logarithmic velocity control, proportional acceleration control, deadband limits, and a variety of digital filtering techniques. Additional self-diagnostics are to be incorporated including current monitoring on each motor.

One of the most promising features of this controller is that it would solve a growing and substantial problem for powered wheelchair users: the congestion of assistive devices on their chair. Each new aid typically requires special attention to make the device accessible to each individual. The joystick or other interface used to drive the chair also can access a variety of other functions. Future plans include incorporating several devices in this manner including remote environmental control and other aids through the RS-232C interface.

Development of a Linear Synchronous Motor for Wheelchair Use

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The Linear Synchronous Motor (LSM) is a wheelchair drive system designed to take advantage of recent high tech advances in motor controls to implement a wheelchair drive system that is less expensive, more efficient, requires less maintenance, is lighter weight, and will perform with optimum efficiency at any speed on any terrain. This motor will be built into the circumference of a wheelchair wheel where the wheel becomes the rotating member of the motor, and the coils that control this rotation will be mounted onto the frame. Thus, there are no moving parts in this system but the wheel itself. It is intended that this system eventually become an integral part of an intelligent computer-controlled drive train for powered wheelchairs.

The purpose of the current contracted research is to design, build, and bench test a single LSM motor on a wheelchair wheel.

Progress — Money was received and work began on this project on April 1, 1985. During the first two months, the research team worked out a rough

mathematical model of the motor design. Based on this initial motor design, the team also designed and ordered parts for the microprocessor-based controller which will be required to drive this motor. Initial mechanical design of the motor also has been done and parts ordered. A more detailed mathematical model of the motor is being designed; however, the computer needed for this work has not been received as of this writing.

Future Plans — The system will be constructed in the mechanics lab at the Atlanta VAMC as soon as parts are received. The motor windings will be wound by the local Cleveland Electric Company. As of this writing none of the materials ordered have arrived, however most of the parts are expected within a few weeks.

After construction, initial tests will be conducted to verify the mathematical model and the feasibility of using this particular design for wheelchairs. Any problems in the design will be studied with respect to the overall design and, if possible, a redesign will occur which will attempt to remedy the problem. Then, final tests of efficiency, torque, ease of control, and reliability will be performed as best possible on a bench prototype. These results will then be compiled and evaluated with respect to the feasibility of using the LSM as a power train for powered wheelchairs.

Manual Wheelchair with Anti-Rollback Wheel

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Sponsor: VA Rehabilitaton Research
and Development Service

Purpose — The manual wheelchair with anti-rollback is a completed project which involves the design of an anti-rollback wheel for manual wheelchairs. The system is transparent to the user, i.e., it is controlled entirely through natural movements in using the wheelchair.

Progress — Two patents have been granted on the initial and advanced designs of the system as previously reported.

Future Plans — As efforts develop to establish a national center for evaluation and testing, this work can proceed. Until national guidelines have been established and funds made available for evaluation and testing, the final phase of field evaluation cannot be completed.

University of Virginia Rehabilitation Engineering Center

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Sponsor: National Institute of
Handicapped Research

Purpose — The Rehabilitation Engineering Center is in the third year of a five year program, conducting research on wheelchairs and seating for the disabled. Some of the seating studies are contracted to the University of Tennessee Rehabilitation Engineering Center at Memphis.

The emphasis at the Rehabilitaton Engineering Center is to conduct technical studies on all aspects of wheelchair and seating design and function that will lead to a better understanding of the principles involved and hence contribute to improved design, fabrication, and prescription.

Progress — Recent work on specific tasks includes:

1) A study on the effects of mechanical advantage on propulsion efficiency with handrims has been completed. Typically, efficiency increases if the handrim is geared to rotate at about half the speed of the wheels;

2) A study on the effects of seat position on propulsion performance has indicated that there is little effect for levers within the range studied, but seat position is an important factor when using handrims. Better results are obtained with the seat moved further back than normal;

3) EMG activity has been studied with various seat positions using lever propulsion. The muscles used are highly dependent on seat position;

4) The effects of lateral slope on wheelchair performance has been studied on the treadmill and an analytical formula developed indicating double the effort for a two-degree slope;

5) A method for recording seat and back contours has been developed and implemented. Information on these contours has been integrated with pressure data and will be used to determine appropriate cushion shapes for modular seating;

6) The effect of hip position on tone and function has been studied using EMG activity. Subjects for the study have been children and young adults with cerebral palsy and data analysis focuses on muscle tone and upper extremity function;

7) Anthropometric data of persons with disabilities have been collected routinely at the seating clinic at Charlottesville and Memphis. In addition, optimum seating configuration for these persons has been recorded based on clinical judgment. When analyzed, the information will be useful for seating design;

8) A survey has been made of various fitting and measuring techniques and a uniform terminology developed. Adjustable fitting seats have been constructed for clinical use;

9) Caster shimmy studies have continued to determine the effect of friction and viscous damping and the effect of tilting the caster axis;

10) Three commercially available sprung forks have been examined to determine their natural frequencies and the effect on rider comfort and frame stresses;

11) Stress analysis of wheelchair frames has been continued. Points of maximum stress have been identified for three wheelchairs and verified with strain gauges. A program S/SAM™ has been demonstrated for use with personal computers;

12) Wheelchair component life spans have been examined using strain gauge measurements. The effect of four different caster forks was studied showing that the reduction in natural frequency can result in increased fatigue life;

13) The problem of directional instability associated with rear caster wheelchairs has been examined and an analysis of the destabilizing moment developed;

14) Dynamic brakes for manual wheelchairs have been examined and a survey of owner needs conducted in cooperation with the Paralyzed Veterans of America indicating two-thirds of the respondents desire such brakes;

15) Seven different materials have been tested to determine their suitability for non-pneumatic tires to decrease rolling resistance. The hysteresis loss factor is a major contributor to rolling resistance;

16) A choke coil has been designed and tested to improve electric motor efficiency when controlled with pulse width modulators. Improvements of up to 39 percent were observed for indoor use. Noise is also reduced;

17) The water loss problem in NICAD batteries has been examined. Starved electrolyte and gel type lead acid batteries are being tested;

18) A battery monitor that keeps a log of current flow during charging and discharging and estimates the percent capacity, based on this and open circuit voltage, has been designed and is under test;

19) An adaptive controller for wheelchairs to provide optimum time response to velocity commands for varying load conditions is under development. The velocity response is excellent but problems remain in switching to each of the four possible modes;

20) Considerable work has been done with respect to wheelchair standards for ANSI and ISO including rolling resistance, the coefficient of friction, seating dimensions, fatigue testing, and impact testing;

21) Wheelchair product design has included modifications to the NASA-UVA composite wheelchair, a simplified version of the lever drive system, a body steering concept, and the first prototype of a wheelchair utilizing the Balans seating posture.

Seating Systems for Body Support and Prevention of Tissue Trauma

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The goal of this project is to investigate the factors that influence the development of pressure sores and postural deformities in the seated spinal cord injured individual and to develop seating system components that help to reduce the incidence of such problems. Present efforts are testing of seat cushion and postural trunk supports (low back) on sitting balance, upper extremity function and objective interface sitting pressures. In our initial work with low back support, interface pressure measurements show drop of 5 mm Hg under the ischial tuberosities in 23/26 patients. While these data are preliminary, they have clinical significance to prevent tissue trauma on the ischial tuberosities.

A study has been initiated to investigate how various thicknesses, shapes, and sizes of low back cushions influence pressure distribution, trunk balance, and user comfort. These data will be analyzed to develop low back cushion specifications and guidelines for prescription.

Maintenance Free Battery

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Sponsor: VA Rehabilitation Research and Development Service

Progress — A good deal of equipment in use at this hospital, including patient movers and wheelchairs depend upon batteries as the power source. Thus, the type of battery used is critical to the performance of the equipment. Although the manufacturers of wheelchairs specify that DEEP CYCLE batteries be used, it appears to be standard practice that automotive batteries are used. DEEP CYCLE

batteries are built with fewer, but heavier lead plates made of a more dense material and are designed to deliver lower currents continuously for many hours resulting in greater range and power. The denser lead plate material is capable of withstanding as many as six times the number of discharge-recharge cycles as an automotive battery. The YUASA NP battery was recently introduced in the market. This battery is air transportable and embodies all of the positive features of DC batteries and is also maintenance free. Because of its unique electrolyte suspension system, this battery can be used in any position without loss of capacity electrolyte or service life.

To obtain maximum efficiency and long life of batteries, simple guidelines should be followed: 1) determine correct battery size and type; 2) utilize the proper charging equipment; 3) proper maintenance helps eliminate premature battery failure. An ideal battery for a 24 volt system (2-12 volt batteries) wheelchair would be a battery that is lightweight, compact, sealed/maintenance free, air transportable, low self-discharge rate—extended shelf life, operational in any position, capable to meet performance requirements as set forth by manufacturers of wheelchairs.

A battery that meets these specifications is a YUASA maintenance-free rechargeable battery. The cost of a YUASA battery (purchased in lots of 50) that would be suitable as a replacement for the now used 22NF series is $57.97. Purchasing larger quantities would reduce this cost considerably. The use of DEEP CYCLE batteries and appropriate battery chargers would be cost-effective and result in more satisfactory wheelchair performance.

New Designs for Personal Lifts

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Many wheelchair users need help transferring in and out of their wheelchair. Sometimes all they need is help from another person. But often a hydraulic or electric lift is required. These lifts are heavy and cumbersome, and a nuisance to transport when traveling.

Progress — Our "PROTEUS Lift Chair" makes life easier for people who need lifts for wheelchair transfers. PROTEUS combines the functions of a powered wheelchair and a hydraulic lift into one, compact unit. We redesigned the chassis of a powered wheelchair to provide a socket that can hold a detachable hydraulic lift. A person can be transferred from the wheelchair by placing him/her on a sling, attaching the lift to the sling and hoisting him/her clear of the wheelchair seat. Once the person is clear of the wheelchair seat, it can be swung out of the way, and he/she can be moved into the desired position and lowered into place.

When the lift is not needed, it can be easily removed and PROTEUS becomes a standard powered wheelchair that can be used either indoors or outdoors. Since PROTEUS chassis has a shorter wheelbase than most other powered wheelchairs, it is also very maneuverable.

A working prototype of PROTEUS is now available for evaluation, and we also have been in contact with wheelchair manufacturers regarding future plans for manufacturing it.

Mapping the Buttock-Cushion Interface Contour with Ultrasound: Significance in Seating for Pressure Sore Prevention

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Purpose — Clinical problems associated with the management of patients susceptible to pressure sores present a major challenge for the rehabilitation team. Spinal cord injured persons are at a particularly high risk for tissue breakdown. Methods for prevention of pressure sores includes first identifying areas of high pressure between the body and support surface and then selecting or fabricating a cushion that will redistribute forces over a larger surface area and thereby reduce pressure peaks and gradients. However, the capacity to distribute the pressure uniformly at the support interface does not depend only on cushion properties; rather it is clear that body build, weight, height, size and shape of bony prominences, and tissue resiliency are some of the factors that govern pressure distribution at the buttock cushion interface. An indirect measure of the latter may be obtained from the indentation contour of the buttock cushion interface. Data on interface contour have not been available till recently.

In the present study, a technique for mapping the three-dimensional contours of buttock-cushion interface and pressure has been proposed. The three-dimensional contour of buttock-cushion interface will be accomplished using an ultrasonic dimension gauge mounted on an X-Y positioning system. Pressure contour will be measured using a TIRR pressure evaluation pad. Measurements will be made on normal, quadriplegic, and paraplegic subjects, and differences in seating pattern will be described quantitatively for the first time.

Progress — A special chair has been designed and fabricated using 2 cm diameter stainless steel tubing. The back, arm, and footrests are similar to those on a standard wheelchair. The seat is replaced by a 2 cm thick plexiglass sheet with a 30 cm $\times$ 30 cm hole cut in the center. A thin sheet of plexiglass placed over the square hole forms the support surface for the gel cushion. The dimensions of the PVC gel cushion to be used in this study are 40 cm $\times$ 40 cm $\times$ 3 cm.

The positioning of the ultrasonic transducer is accomplished by two precision orthogonal sliding assemblies driven by high resolution stepper motors (0.9 degrees per step) under the control of an IBM CS9000 instrumentation computer. The positioning system is housed in an enclosure. In order to achieve good coupling and friction-free sliding between the ultrasonic transducer and the thin plexiglass plate, an enclosed water coupling system has been designed and fabricated. The coupling system includes a cylindrical cup for housing the transducer. An O-ring attached to the top surface of the cup facilitates smooth motion of the cup across the bottom surface of the thin plexiglass plate. A water tight seal is maintained by a spring loaded mechanism which gently presses the cup against the plexiglass plate. During data acquisition, the cup is filled with degassed, distilled water and connected to a reservoir under pressure.

In conjunction with the buttock-cushion contour information, pressure measurements are accomplished using a pressure evaluation pad (PEP). The PEP is an electromechanical device and contains a 12 $\times$ 12 matrix of pneumatically controlled flat contact switches enclosed in a mylar bag. The pad has been interfaced with the IBM CS9000 computer through an interfacing circuit via an analog to digital converter. At each inflation pressure, switch closures are read by

the computer and are displayed as a matrix of binary values. The sensing pad is placed between the subject and the gel pad. The pneumatic system is activated by an air pump and the pressure is monitored using a pressure gauge. By varying air pressure within the pad and recording the corresponding matrix of switch closures, it is possible to obtain the pressure contours under the buttocks and specifically under the bony prominences.

Computer software for acquiring buttock-cushion contour data has been completed. Software for acquiring pressure contours from the pressure evaluation pad is also under development. Development of three-dimensional graphic display software is in progress.

It was our original intent to modify the seating system used in our earlier two-dimensional system. However, the scanning system could not be housed within the framework of the original wheelchair seating system. Therefore, a special chair was designed and fabricated from stainless steel tubing. However, the project should be completed as per our original time table.

Evaluation of Powered Wheelchairs and Their Steering Systems

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — As a follow-up to an earlier project in which a method of power steering was developed for certain types of powered wheelchairs, a formal evaluation of new wheelchair designs and power steering for wheelchairs is about to begin. For this evaluation, a special van-compatible wheelchair manufactured by Mobility Engineering, Inc., a high-performance conversion of an Everest and Jennings (E&J) Model 3P chair and a standard E&J Model 3P are being equipped with power steering. The special types of chairs will be compared with the standard E&J Model 3P, and the advantages and disadvantages of power steering on each type of chair will be determined. The hypothesis is that power steering will provide improved stability on laterally sloping surfaces and over rough or hilly terrain.

Progress — The wheelchairs will first be given an engineering evaluation to test them in all conditions under which they are expected to operate. Then, fifteen veterans and others who regularly use powered wheelchairs will be selected as participants. Each participant will test each of the three wheelchairs for one week, using it in all of his or her daily activities. Based on comments from the users and observations by the evaluation team, the wheelchairs will be modified and improved to the extent feasible, after which the same participants will test each of the chairs for another week. Prior to and following each evaluation period, each participant will be required to operate each chair through a prescribed sequence of maneuvers and conditions to provide additional objective and subjective data.

Safety problems with the power steering were encountered in the initial attempt to begin the evaluation. These problems have been corrected and installation of the modified power steering system on the E&J chairs is complete. Installation of power steering on the van-compatible chair is underway, along with an effort to recruit a suitable technician to carry out the evaluation.

A Heelstrap Retractor and a Shock Absorbing Seat Suspension System for Wheelchairs

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The heelstrap on many unpowered wheelchairs can lead to situations that are both troublesome and hazardous. In order to alight from the wheelchair, the user must position the foot pedals vertically. This can be done only if the heelstraps are forcefully pushed toward the front of the foot pedal. If this is not done, the heelstrap prevents vertical positioning of the foot pedal. The foot pedal then presents an obstacle that could trip the user as he alights from the chair.

The heelstrap retractor solves this problem by forcing the heelstrap to the proper position as the foot pedal is raised. This is accomplished with an inexpensive coil spring that is easily attached to the chassis of the wheelchair. A thin metal finger at the end of the coil spring contacts the heelstrap. Raising the foot pedal causes the finger to rotate, pushing the heelstrap forward and out of the way. This eliminates potential hazards and makes it easier to vertically position the foot pedal.

Road shocks and vibrations pose a crucial problem to users of unpowered wheelchairs. The severity of this problem can range from an annoyance to aggravation of pressure sores (decubiti). Many suspension systems have been posed to minimize the problem, but they require extensive modification of the wheelchair. Manufacturers are reluctant to adopt such designs.

Our design does not require such modifications to the wheelchair. Rather than adding suspension to the chassis, as in previous designs, we have suspended the seat. This suspension system is accomplished with spring-loaded, post-shock absorbers located between the upper and lower parts of the wheelchair chassis. A shock absorber is located near each corner of the seat. The shock absorbers dampen vibrations to the lower frame.

H. Personal Licensed Vehicles

[See also pg. 161]

A Driving Simulator for the Physically Disabled Person

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The Driver Simulator is a system designed to facilitate therapeutic evaluation of the hardware to be retrofitted to a disabled driver's vehicle. It consists of a full-scale mock-up of the necessary portion of a van interior including steering wheel, dashboard, seat, and other items necessary for driving. In front of this dashboard is a large screen monitor driven by a modified Apple IIe microcomputer on which the simulation takes place. This system is so designed to allow easy changing of hardware configurations and thus allow an individual to be evaluated for many different retrofit systems.

Progress — In September 1983, the initial design for the Driver Simulator was completed. A summary report was written and the engineering drawings were

prepared. Space for the construction of the project was arranged but no construction has started due to shipping delays in the arrival of the components. The software for this system is still under development.

Future Plans — The system will be constructed in the mechanics lab at the Atlanta VAMC. Materials for the frame have arrived and the remainder of the parts can be purchased locally. The system also may be used as a test bed for development of new driving aids for physically disabled persons.

Adaptive Systems for Disabled Ultralight Pilots

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Progress — Prototype braking, steering, seating, and positioning systems for the disabled Ultralight pilot have been designed, fabricated, and test flown.

In addition to the original designer of the Ascender Ultralight, three commercial firms have agreed to work with this project to make commercially available systems suitable for use by the disabled pilot. A pre-production fiberglass/kevlar adjustable seat system is being manufactured in Dallas, Texas by a firm expert in the use of lightweight composit construction. A safety harness manufacturer who participated in design revisions of pre-production seating/positioning prototype has agreed to produce the pre-production harness system for seating attachment as well as the safety harness for pilot crash protection. A leading manufacturer of ballistic parachute systems has agreed to make design changes (which may be required for disabled pilots) available commercially.

In transferring into the Ultralight, the fuselage tubes of the aircraft being used are 28 inches off the ground and 14 inches wide. For the severely disabled individual this presents serious problems in transferring into the aircraft. The seating and positioning system has therefore been designed to facilitate the transfer using a level transfer and sliding board. In this way, it is possible for a spinal cord injured C5/6 quadriplegic to transfer into the aircraft with one helper.

Seating and positioning is vitally important for safe functioning in an Ultralight aircraft in turbulent air conditions. For many pilots positioning is of critical importance for safe operation of the controls. Any movement of the body away from the ideal control position could potentially cause loss of control. This part of the project has absorbed most of the effort to date. For the initial part of the project, including flight tests, a boat seat was modified to fit into the Ultralight. Additional back support was added as was head support, which was quickly discarded as unnecessary and a source of vibration. The seat requires firm anchorage for positive and negative G forces as well as significant adjustability fore and aft, height adjustment, and tilt adjustment. (All seat mounting straps and safety harnesses will be manufactured to safety specifications of 2400 pounds-force per strap). In order to provide negative G for security, a cage has been constructed passing directly under the seat and providing extra protection for the legs in the case of a crash landing that causes the front gear to collapse. For leg and foot positioning, a simple adjustable calf platform provides a secure/safe positioning system.

The system has been shown to have sufficient adjustment to fit able-bodied people from 4 foot 11 inches tall, weighing 110 pounds to a 6 foot 4 inches tall, 230 pound, C6 quadriplegic. Following this initial work, a re-design has been done on the seating system and a pre-production lightweight fiberglass/keflar adjustable seating system is being manufactured in Dallas. The manufacturer of this pre-production prototype is interested in producing the seats as part of a commercialization program.

Modification to the ballistic parachute triggering system has yet to be carried out but will be relatively simple and will be readily incorporated into the production model by the manufacturers who have agreed to this in principle.

The system has not been ordered because the weight of the system will put the Ultralight well over the legal limit. In order to tackle this problem, a presentaton has been made at an FAA public meeting on Ultralight legislation arguing for a weight allowance and other devices to give equal safety to disabled Ultralight pilots. A formal petition to change FAR-103 will be lodged in due course.

The Unistik Vehicle Controller: A Unique Approach to Driving for Severely Handicapped Individuals

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Functional motor vehicle control for tetraplegics above the C6 level or people with only one functioning extremity has heretofore been only very limitedly feasible, difficult to obtain, and exceedingly costly.

Progress — The Unistik Vehicle Controller (UVC) was developed by Johnson Engineering Corporation in conjunction with and supported by the National Aeronautics and Space Administration and the VA. It consists of: 1) the driver interface, a complex joystick mechanism which converts the driver's control movements into electronic signals; 2) the signal controller, which processes and modifies the signals from the driver interface and sends them to the vehicle interface; 3) the vehicle interface, electromechanical actuators which move and position the steering shaft, brake pedal, and accelerator pedal in response to the electronic control signals; and 4) a self-diagnosis and monitoring system to warn the driver of malfunction and activate redundant mechanisms.

Characteristics of the joystick control including sensitivity, centering, feedback, or other qualities may be modified by altering software in the signal controller, thus providing reversible adaptation to individual patient needs. The UVC system is easy to control with one hand, lightweight, safe, reliable, easy to install, and can be adapted to a wide range of disabilities. Ongoing development in process includes secondary controls, reliability and safety testing, refinement of monitoring system, and adaptation of driver interface for a wide range of disabilities. The UVC is a unique system that represents a potentially highly functional and cost-effective solution to the problem of vehicle control for severely handicapped persons.

I. Functional Electrical Stimulation

1. General

External Control of the Neuromuscular System

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Sponsor: American Paralysis Association

Purpose — The application of electrical stimulation toward restoration of lost movement due to stroke and spinal cord trauma is investigated in a systematic approach. Although primitive type of muscle contraction is possible even with simple transcutaneous stimulation of the motor point, an accurate and well-coordinated movement of an extremity joint requires complex control of several physiological processes such as action potential rates, motor unit recruitment, synergy of antagonistic muscle pair and proprioceptive, and tactile and kinesthetic feedbacks.

Progress — The technique developed utilizes dual electrode assembly placed on the muscle nerve; one controls the action potential rate with pulses of low frequencies (20-60 pps) and the second electrode controls recruitment of motor units according to their size with high-frequency pulses. The other physiological elements associated with joint control are incorporated in the overall system design.

Recent studies in the laboratory established the recruitment model of the muscle, the optimal gain and model of the proprioceptive/reflexive feedback required, and the combined time and frequency response of the models.

More recent studies focused on using the myoelectric signal of the electrically stimulated muscle as the proprioceptive/reflexive feedback mode. A sophisticated recording and filtering technique was developed to eliminate artifacts from the dual stimuli, and a signal processing employing EMG instantaneous median frequency and RMS value successfully correlated the signal to the muscle force profile.

Neuroaugmentive Procedures for Modification of Abnormal Motor Control in Patients with Spinal Cord Injury

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Purpose — Sixty patients with muscle hypertonia after spinal cord injury have undergone spinal cord stimulation (SCS). These patients had spinal cord injuries (SCI) ranging from C2 to T12. Electrodes were placed above, below, or above and below the lesion in the posterior epidural space for a period of at least 3 days during which time stimulation pulses, typically of 3 to 5 MA amplitude and of 0.2 MS duration at 30 Hz were applied. The effects of SCS were monitored by recording motor unit activity with surface electrodes over leg muscles during an examination of segmental and suprasegmental spinal cord activity, in addition to patient reports and neurological evaluations. The results of spinal cord stimulation can be divided in four distinct categories. In Group I, consisting of 17 patients, or

28 percent of the entire group, the effect was characterized by marked suppression of muscle hypertonia and so-called spontaneous spasms. In Group II, the effect of spinal cord stimulation on muscle hypertonia was moderate as evidenced by the suppression of the tonic but not phasic features of spasticity. This was observed in 20 patients, or 33 percent of the total. In Group III, neurological and neurophysiological evaluations revealed only a marginal effect. The condition of this group of nine patients (15 percent) did not improve significantly. In Group IV, consisting of 14 patients (23 percent), there was no effect.

Preliminary Results — The above described results have led us to conclude that in patients with cervical lesions a marked effect is most likely to occur when the residual functions of ascending and descending systems are preserved. A possible mechanism contributing to SCS in this condition might be the activation of descending inhibitory segmental interneurons via the dorsal column, brainstem, and spinal loop. In patients with thoracic lesions, when the stimulus was applied above the level of the lesion, the effect was marginal in comparison with the marked effect obtained when stimulation was applied below the level of the lesion over posterior structures. These observations suggest that the underlying mechanism in this condition is the antidromic effect of spinal cord stimulation through posterior spinal cord structures.

Functional Neuromuscular Stimulation for Quadriplegic Patients

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Sponsor: Osaka Rosai Hospital

Progress — A very simple system using surface electrodes is being developed for C5 level quadriplegic patients. Our system consists of two-channel stimulators, a toggle switch, and a supplemental orthosis. Distinctive features of our system are that it is very simple and not invasive. Problems of this system are difficulty of placing electrodes and need of supplemental orthosis. Presently, we are preparing to develop an implanted system for these patients.

Neurophysiological Assessment of Changes Induced by Neuromuscular Electrical Stimulation in Stabilized SCI Patients

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Purpose — A number of centers in the United States and Europe have been working on the problems of electrical stimulation for the completely paralyzed spinal cord injured (SCI) patient for over 15 years. Much research and development remains to be done before a system for completely paralyzed SCI patients will be practical. Partially paralyzed patients however, can benefit now from neuromuscular electrical stimulation (NMS) for muscle strengthening and suppression of muscle hypertonia (spasticity), and from functional electrical stimulation (FES) for augmenting partially preserved movement.

At The Institute for Rehabilitation and Research in Houston, Texas, a center for clinical use and evaluation of the effects of FES has been organized as a part of the Program for Restorative Neurology. A recent study of a group of five stabilized SCI patients who used NMS and FES daily for six months found a reduction in spasticity, improved volitional muscle activity, better walking patterns, and increased gait endurance compared to their prestimulation state.

The nature and extent of changes in neurocontrol mechanisms induced by extensive use of NMS and FES in ambulatory SCI patients have not yet been described or documented. Thus, the goals of the program are to study the effects of the use of NMS and FES in partially paralyzed patients, to describe criteria for selecting patients and to examine the underlying mechanisms which are responsible for long-term stimulation effects.

The proposed research, to be conducted over a three-year period, will be carried out on approximately 10 SCI patients per year. It will include those who have the ability to stand and take a few steps. Patients selected will be between the ages of 18 and 55, with good general health and cardiorespiratory function. They must have completed a physical therapy program prior to the study.

Evaluation of the patients will be by interviews, patient questionnaires, staff observations, physical therapy evaluation, clinical neurological evaluation and clinical neurophysiological evaluation. The clinical neurophysiological evaluation will include the assessment of muscle hypertonia by an isokinetic dynamometer, assessment of segmental phasic and tonic stretch reflexes, cutaneo-muscular reflexes, long loop reflexes and postural and equilibrium control, and gait studies employing simultaneous recording of muscle activity, joint movement and studies of foot floor contact. A program of NMS or FES will be tailored according to each patient's particular needs. Stimulation goals include reduction in spasticity, muscle strengthening for both voluntary and stimulated movements, increased range of motion, standing, walking, improved patterns of gait, and improved endurance in walking.

Progress — In each patient the program will start with NMS in order to suppress spasticity in certain muscle groups and to thereby achieve initial mobilization goals and to modify existing gait patterns. As the patient becomes competent in the use of the equipment (application of the electrodes and adjustment of the stimulus strength), FES will be added to the ongoing NMS program when further improvement of gait can be achieved. At intervals of one month, functional changes in walking will be assessed. At three-month intervals, a full assessment will be made by repeating the initial battery of clinical and clinical neurophysiological tests. Patients who have shown beneficial changes at that time will then be tested over a period of up to four weeks for the persistence of these neurocontrol patterns after withdrawal of the stimulation. Following completion of the six-month-testing period, patients will be placed into the ordinary clinical routine with the addition of annual follow-up evaluations.

Responses to questionnaires and other usage factors will be assessed to determine the perceived level of utility of the stimulators. Measurement of gait patterns and quantification of hypertonicity will serve as confirmation of beneficial changes. Of great importance will be the correlation between the effects achieved and the category of the patient according to the level, severity and

extent of his spinal cord injury, i.e., the degree of neurocontrol. This comparison will serve as a basis for the development of clinical neurophysiological criteria which can be applied in the selection of appropriate SCI candidates for FES.

Influence of Continuous Electrical Stimulation on the Spinal Cord Motor Neurons

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Sponsor: Paralyzed Veterans of America, Vaughan Chapter

Purpose — Applied electric fields have been reported to facilitate regeneration or regrowth of injured peripheral nerves and severed spinal cord axons. We are conducting this study to evaluate what stimulation parameters might be best.

Progress — For the study we anesthetized female Wistar rats, 200 to 250 grams in weight, with a 6 percent chloral hydrate, then performed laminectomies to expose T10-T13 levels of the spinal cord. We inserted tantalum electrodes into the cords at a depth of 1mm and spaced 2cm apart with the current traveling in a head-to-foot direction. The stimulator was sutured subcutaneously. For stimulation we used monophasic pulses of 130 mV, 0.3 msec duration and 120 msec apart. After three months of continuous stimulation, we sacrificed all animals by perfusion with Karnovsky's fixative, then removed the spinal cords, cut them into small pieces, and processed them for the electron microscopic examination.

After three months of continuous electrical stimulation, the animals did not exhibit any motor deficits upon gross observation; they appeared normal in all respects. However, when they were allowed to walk on a smooth surface, like X-ray film, their hind limbs showed a slight deficit in grabbing as compared to non-stimulated animals. We also noted some tissue disruption of the spinal cord at the site of anodal electrode insertion. Our electron microscopic examination of motor neurons located between the two electrodes and below the cathode showed typical-appearing neurons, glia, and synaptic structures. However, upon further observation, we noted an alteration in the stacking of individual strands of rough endoplasmic reticulum and the distribution and quantity of Nissl substance of the motor neurons.

Computer-Controlled 22-Channel Neural Stimulator for Functional Electrical Stimulation

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — It has been possible to modify the NUCLEUS Multi-Channel Implantable Hearing Prosthesis (Nucleus Ltd., Lane Cove, Sydney, Australia) into an implantable 22-channel neural stimulator for use in functional neural stimulation (FNS). This is being designed to be used for patients with upper motor neuron lesions following spinal cord injury or stroke. A new computer software program was developed by Dr. Richard Eckhouse of MoCo Inc. for use with a desk top microcomputer that was connected to the speech processor interface (SPI). The SPI in turn activates the external antenna which overlies an implantable receiver-stimulator (RS). The RS module was modified by deleting the cochlear lead electrode and substituting 22 individual insulated wires leading to a D connector for our laboratory use in animals in our initial pilot study.

Progress — The pilot study undertaken in 1985 has shown that this 22-channel stimulator can be controlled by the computer program to activate peripheral nerves in the leg of anesthetized rabbits so that the muscles can be fully controlled and contracted to move the joints of the lower extremity. The software program was able to activate single or many electrodes so that a single muscle could be activated independently or that a group of muscles could be activated causing co-contraction at a joint such as the ankle or simultaneous movements of the joints of both legs at the same time. A program has been started allowing data to be collected from human peripheral nerves at the time of amputation. The parameters of stimulation producing maximal contraction of leg muscles are well within the power output of the stimulator (maximum 2.3 mA, 400 msec, 20-50 Hz).

Future Plans — The pilot project for 1986 is in two parts: 1) To continue building up data from the stimulation of human nerves at surgery (such as amputation, vascular and hip prosthesis). The choice of electrodes and their testing also will be carried out during the acute surgery. The constancy of the radio stimulator also is being checked weekly for its power output under various temperature changes; 2) Dr. Richard Eckhouse (MoCo Inc.) with the cooperation of Nucleus Ltd. is undertaking a design and construction of a belt-worn microcomputer containing software programs capable of producing patterns of exercising, standing, walking, and stepping in patients with paraplegia and stroke.

Functional Electrical Stimulation

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Sponsor: Regency Park Centre for Young Disabled

Purpose — Denervated or partially innervated muscles can be electrically stimulated into action. This exciting new technique requires further investigation regarding its value in retraining muscle action following spinal cord injury, and in regard to its orthotic application.

Our aim is to introduce functional electrical stimulation (FES) into our treatment programs in a controlled manner in which physiological and functional benefits are monitored.

Progress — The effects of functional electrical stimulation will be studied in two areas:

1) *Upper Extremity Muscle Strengthening of Spinal Cord Injured People.* In the preliminary phase, we will purchase two FES units (left and right), a myometer, and will fabricate feedback orthoses for elbow and wrist. We also will purchase a computer and develop software for display feedback of wrist and elbow flexion and recording of results.

In the experimental phase, approximately six subjects will be studied over a 12-month period. The experimental design will consist of alternative three-to-four month periods of FES assisted exercise and isotonic exercise, with concurrent weekly measurements of strength and range of motion by a second therapist who will be unaware of the subject's muscle strengthening regime.

In the concluding phase, we will publish results in a professional scientific journal and, if the technique is successful, introduce it into regular treatment programs.

2) *Orthotic Gait Assist Applications*. In the preliminary phase, we acquired components, designed and fabricated a 2-footswitch 2-channel stimulator suitable for applications in gait training.

In the experimental phase, the application of functional electrical stimulation to dorsiflex and evert the feet of ambulant cerebral palsied children has been described, and we will compare this form of orthotic application with conventional orthoses with particular regard to any carry-over effects.

In the concluding phase, we will publish results in a professional scientific journal and, if the technique is found to be successful, introduce it into regular treatment programs.

EMG as Force-Feedback in Closed-Loop Functional Electrical Stimulation

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — While a number of experimental functional neuromuscular stimulation (FNS) systems have been reported to restore locomotor function to paraplegics and grasping to quadriplegics, few if any FES devices exist that patients will accept in daily living; none are commercially available and clinically prescribed. Our objective is to develop a closed-loop FNS system to improve dynamic force and position control which in turn would increase patient acceptance. Feedback control of movements should increase repeatability, reliability, and smoothness of responses; reduce mental and physical effort; and facilitate coordinated control of agonist and antagonist muscles of several joints.

Progress — Our approach is to provide muscle force feedback by extracting from the stimulated EMG response information related to muscle force and metabolic state. Nerve cuff stimulating and intramuscular stimulating and/or recording electrodes will be used. Stimulus artifact will be examined and techniques for separating it from force information determined. The shape and variability of the EMG response and its dependence on electrode parameters, particularly orientation, will be analyzed. Computational techniques for transforming the EMG signal into force output will be evaluated. An FNS controller will be implemented using force and position feedback to achieve dynamic reciprocal control of the gastrocnemius and tibialis anterior muscles of the cat ankle joint.

EMG and force data have been collected from several rats and one cat. We are using a WPI Iso-III optically isolated stimulus unit capable of converting an arbitrary biphasic signal into constant current output. When stimulating and recording from separate 7-stranded stainless steel teflon coated intramuscular electrodes (Medwire #316SS 7/44T), computer controlled monophasic stimulus pulses (50-100 us width, .05 ua to 10 ma) resulted in minimal stimulus artifact which typically disappeared within 1 ms following the stimulus. Polarization of the stimulus electrodes lasted tens of ms. Thus, contamination of the EMG can be prevented by delaying EMG sampling by 1 ms. This is acceptable since the primary EMG waveform during intramuscular stimulation occurs between 1 and 3 ms following the stimulus onset. (Force onset began about 10 ms after stimulus onset and lasted until 50 to 100 ms).

It has been found necessary to digitize EMG data at 10 khz and force at 1 khz, for which special data acquisition routines have been written. These routines allow trains of pulses of varying interval, width, and amplitude to be applied to a single muscle. EMG responses show considerable variation in shape. They may be bi-or triphasic, and in some cases change from bi- to triphasic as a function of increasing amplitude, presumably due to recruitment of additional motor units. We are in the process of systematically investigating these changes as a function of stimulating and recording electrode orientation and location.

We are also in the process of building a restraining table for the cat hindlimb with which the ankle joint can be manipulated and ankle forces measured.

I. Functional Electrical Stimulation

2. Upper Limb Applications

Implantable Systems for Stimulation of Skeletal Muscle (Guinea Pigs, Dogs)

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Sponsor: National Institutes of Health

Purpose — The objective of this project is to develop an implantable stimulator system for electrical excitation of paralyzed skeletal muscle. This system will be utilized by high level (C5 and C6) spinal cord injury patients to provide controlled grasp and release in the hand. In this application functional neuromuscular stimulation has previously been demonstrated to be effective by employing chronically indwelling percutaneous electrodes. Through the use of the implantable system, we expect that the ease of use of the system and its reliability will be improved, leading to greater independence for the quadriplegic patient.

Progress — The objective of development of the implantable system will be met by: 1) development of circuitry using a high density of integration to perform the stimulation function; 2) development of techniques for encapsulation of the stimulator in a hermetic package suitable for extended periods of implantation (greater than 5 years); 3) development of stimulation electrodes and lead wire interconnections which are suitable for use with the implantable stimulator; 4) development of a programmable control transmitter which is worn externally by the subject and regulates the output of the implant stimulator in response to the control signals generated by the subject; and 5) evaluation of the entire system and individual subsystems (e.g. electrodes, packaging) *in vitro* and *in vivo*, and modification of the design where necessary. The principal applicaton of this study is the upper extremity in the quadriplegic subject. However, the technology being developed in this project is expected to be directly applicable to other neurological deficits, such as stroke and cerebral palsy, thus enabling researchers and clinicians to have a powerful new technique more available for rehabilitation of motor function.

Myoelectric Controller for Orthotic/Prosthetic Systems (Cats)

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Sponsor: National Institutes of Health

Purpose — The aim of this project is to develop the techniques and instrumentation necessary for the high spinal cord injury and amputee population to obtain multiple command control signals for use in activation of upper extremity orthotic and prosthetic appliances. Emphasis is placed on producing command signals that are proportional in nature and with sufficiently high signal-to-noise ratios for the execution of finely controlled movements. As a result of this research, we will develop a command control scheme which optimizes the performance and fidelity of the output device.

Progress — The performance of this control scheme will be demonstrated in an animal model. Specifically, this project will produce a complete myoelectric controller system. This system will consist of two major subsystems: 1) an implantable intramuscular electrode array linked to a multichannel telemetry device; and 2) a telemetry receiver/myoprocessor. The latter subsystem will be a compact microprocessor-based unit that can be incorporated into a portable functional electrical stimulation system or powered prosthesis. The telemetry device will be available in two optional packaging configurations: a self-contained RF-powered telemetry device or a telemetry device with a separate RF power module receiving antenna.

Functional Neuromuscular System for Upper Extremity Control

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The objective of this project is to develop systems for functional neuromuscular stimulation and implement and evaluate their effectiveness in providing restoration of upper extremity function in the high level spinal cord injury subject. The studies performed in the past year have focused on the development of the system hardware and software for implementation of implantable stimulator systems into human subjects. These developments are in the implantable stimulator device and in the external control unit used to regulate the implanted unit.

Progress — In the area of implanted stimulator development, circuitry modifications have been designed into our implantable device which will provide for five bit regulation of current amplitude. This amplitude regulation is in addition to the pulse width control (1 usec resolution over a range of 0 to 255 usec) and interpulse interval control (1 msec resolution from 0 to 50 Hz) that has previously been available. Integration of this circuitry on a semi-custom CMOS integrated circuit is presently underway, and fabrication of final circuits are expected to be completed by January 1, 1986. Implantable stimulator units have been undergoing animal evaluation (under support of the NIH), and we expect completion of this phase of testing to be ready for human trials in the first quarter of 1986.

Development of the external control unit has undergone extensive redesign and refinement. The new hardware provides for more versatile processing of input

command control signals, generated by the user, and for regulation of the output stimulus signals. The unit is based on two CMOS microprocessors (RCA CDP 6805E3), one which performs input processing and one which modulates stimulus parameters. The device is able to control two implantable devices to their full capabilities and four implants with more limited capacity for individual control of the ipi and pw of each channel. The design of the external controller is nearly complete, with the exception of the final design of the radio frequency transmitter. The design is implemented in four interconnected circuit boards (modules). The layout of printed circuit boards is partially completed and some modules are under fabrication.

Software to perform the control and modulation functions has been updated from the present version of patient portable device. This software provides for ease of programming the control and stimulation parameters into the portable unit from the laboratory computer system. The software presently functions equivalently to the present patient portable device, but software updates will allow for additional input processing as well as monitoring of device usage and system checking, for example, of broken electrodes or low batteries.

We expect to introduce the new device into clinical usage in January, 1986, in conjunction with percutaneous electrode systems which are presently implemented with our eight clinical subjects, and subsequently with the implantable stimulator system.

I. Functional Electrical Stimulation

3. Lower Limb Applications

Weight Transfer Training Using Biofeedback and Electrical Stimulation in Strokes and Incomplete Spinal Cord Transections

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The hypothesis is that patterned electrical stimulation of lower extremity muscles will facilitate patient awareness of the involved leg, transfer of weight to the leg, and assist therapists in teaching standing balance and weight transfer.

Progress — The method is to design and construct a weight-bearing test device, weight transfer apparatus, force feedback display, and electrical stimulators. Study and control groups will be observed to determine if weight-bearing, gait, endurance, energy expenditure, and ambulation level are altered by patterned electrical stimulation.

The goals are to improve a gait training program for patients recovering from certain neurological conditions, shortening hospitalization time, and providing an improved level of ambulation.

Electrical Stimulation in Cerebral Palsy Hypotonia

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Purpose — Substantial variations of antagonist muscular development related to tone, strength, and size are extremely debilitating in the various gait cycles of cerebral palsy patients. Furthermore, during standing such muscular imbalance results in poor posture, fast fatigue, and its associated secondary implications.

Progress — A study was conducted on selected groups of hemiplegics, diplegics, and paraplegic cerebral palsy patients who are able to walk. All the patients had stronger hamstring muscle groups that resulted in gait and posture with partially flexed knees. The patients received 15 minutes of cycled electrical stimulation of the quadriceps three times a week and were tested for functional performance on the Cybex system before the stimulation program and every two weeks during the program.

Of the 12 patients, 80 percent had substantial increase in quadriceps bulk, strength, and endurance. Parents of the patients reported improved gait and fatigue resistance as well as posture. Of the remaining two patients, no substantial improvements could be recorded, even compared with controls. We suspect that psychological factors, primarily lack of motivation, prevented some patients from maximal performance during the Cybex evaluation.

Patients showing improvement after 6 to 8 weeks were removed from the stimulation therapy for 10 weeks for us to assess whether the improvement was permanent, temporary, or dependent on ongoing stimulation. Cybex evaluation is pending at the end of the 10-week intermission.

Computer Models for Designing FES Systems for Paraplegic Standing and Walking

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Purpose — Restoring motoric function to spinal cord injured persons by functional electrical stimulation (FES) of their paralyzed muscles has been explored for over 20 years. It has been demonstrated that muscles activated by FES can enable paraplegics to rise from a chair, stand, and walk. These pioneering efforts have identified major technological problems prohibiting routine clinical prescription of FES as a means for paraplegics to regain function of their legs. One of these problems is the lack of computer models both for designing FES systems to control standing and walking in paraplegics, and for determining the trade-offs among the different designs. Knowledge obtained from studying these trade-offs should reduce the amount of experimentation needed to develop clinical FES systems for restoring mobility to paraplegics.

Progress — We are developing a computer model based on modern engineering control principles that can be used to study simulated FES induced standing and walking in paraplegics. The model will include the dynamic interactions among the ground, the legs, the torso, the arms, and the static and dynamic properties of the stimulated muscles.

The computer model will be used first to study, design, and evaluate FES feedback control strategies needed to induce stable standing in paraplegics. The

performance of these FES systems will be based on both subjective and objective measures of simulated standing ability. The subjective evaluation will be based on an animated graphics display of a simulated standing paraplegic. The objective measure will be a scalar, or score, based on the FES system's ability to maintain stability and minimize muscle fatigue.

Restoration of Locomotion in SCI Patients Using FES

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Sponsor: University of Strathclyde

Progress — This program has been established in collaboration with the Departments of Electrotechnology at the Universities of Ljubljana and Belgrade. The aim is to evaluate and develop FES orthotics using, for the present, surface electrode technology. The project has so far concentrated on the development of FES aids for standing and walking. It is anticipated that the standing aid will be made commercially available in the near future. Walking aids have been used by some SCI patients, incompletely lesioned at cervical and thoracic levels, to attain independent crutch-aided ambulation. Prototype Hybrid Orthoses have been developed and are being investigated for use by SCI patients completely lesioned at thoracic levels.

Biomechanical and Physiological Evaluation of Paraplegics Activated by Functional Electrical Stimulation

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Sponsor: Israel Ministry of Defence, The Segal Foundation, and the Technion VPR Fund/W. Levenson Fund for Biomedical Engineering Research

Purpose — The safe application of functional electrical stimulation (FES) for the activation of paraplegics requires objective and quantitative means to biomechanically and physiologically evaluate these patients. In this research both these aspects are being investigated: the biomechanical by means of weightbearing during standing and kinematics of the stride during reciprocal walking; and the physiological by parameters such as heart rate, pulmonary function, oxygen consumption, and blood flow.

Progress — FES is being used to generate supported gait in paraplegic patients with traumatic upper-motor-neuron-lesion, between T5 and T12 spinal levels. The quadriceps and gluteus maximus muscles are stimulated simultaneously to achieve a supported standing position, while hip, knee, and ankle flexions are achieved alternately for each leg by stimulating the shank surface at two selected locations. The stimulus used has an intensity of 90 mA, duration of 0.3 msec, and frequency of 30 Hz. Standing and walking of the patients are being monitored in the gait laboratory of the Loewenstein Hospital. The amount of weight-bearing on each foot during standing is established by time integration over a standard period of time of the reaction forces as measured by 'Kistler' force platforms on which the patient is required to stand while taking care to support his walking aids outside the platform area. Gait of the patients is evaluated by means of an electrical contact system, in which time-distance parameters of the stride are being measured. Computer processing of the data acquired is used to obtain objective evaluation of the patients' progress during their training period.

The influence on the cardiopulmonary system of muscular contractions of the paralyzed limbs in paraplegia activated by FES during treatment and the energy cost of standing and walking while using FES as an orthotic aid also are being evaluated. At the end of a training program, heart rate and oxygen consumption of the patients are monitored as follows: at rest; following 30 minutes of FES in the sitting position; following 15 minutes of standing; and during ambulation. Lactic acid level during maximal effort are taken as well.

Preliminary Results — A training method for the activation of the lower limb muscles of paraplegics by functional electrical stimulation (FES) for standing and walking was developed. It consists of a daily program that does not interfere with the normal routine of the patient. The treatment of seven patients, paralyzed from 4 to 30 years and with ages from 26 to 50 years, was applied. In these patients, a good standing position was achieved by stimulating the quadriceps, sometimes supplemented by the gluteus maximus or medius muscles. Gait was obtained by activation of the flexion reflex in a single stimulation and by tilting the trunk. Difficulties during gait were encountered due to the strong adduction of the legs. No mechanical support was required for locking of the lower limb joints. However, to maintain the equilibrium of the body, external support such as parallel bars, walker, or Canadian crutches were used. During treatment, gait improved due to reduction of spasticity and better stability of the body. Biomechanical measurements of weightbearing on the legs indicated values ranging between 41 to 65 percent of the body weight. During gait, a steady improvement of velocity was noted, with a parallel decrease in stance and stride times.

The physiological results indicated a low energy cost of FES in the sitting position and during usage of FES as an orthotic device for standing, confirming the beneficial effect of FES for spastic paraplegics. However, effort invested during ambulation by means of FES was found exhaustive.

It should be pointed out that the low weightbearing on the feet could be the cause for the high energy expenditure due to the extensive involvement of the upper limbs during standing and walking. This can strongly be affected by the posture of the patient in the upright position, which in turn can be controlled either by stimulation of the gluteus muscles or by usage of a brace, both of which are now being studied.

Walking Restored in Paralyzed Man Using Electronic Orthotics

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Research activities in this program are directed toward further development of a neuromuscular orthotics system that will provide paralyzed persons with specific functional activity.

Progress — During the past year, we have addressed the specific concerns of walking speed and the use of walking aids and have begun to investigate the issues of energy expenditure, postural stability, and the ability to safely withstand sudden perturbations.

Six subjects with complete spinal cord lesions ranging from T4 to T11 and no significant peripheral nerve damage were implanted bilaterally with percutaneous intramuscular electrodes in the hip flexors, extensors and abductors, knee extensors, dorsiflexors, and plantar flexors. Stimulation patterns were developed by trial and error on the basis of normal activities of these muscles. Electrical stimulaton was provided by either a laboratory computer or a portable microprocessor-controlled stimulator. Gait patterns were evaluated using gait laboratory instrumentation for foot-floor contact and goniometers for angle measurements at the hip, knee, and ankle. Videotape records of some trials also were made. Metabolic energy requirements for electrically-assisted walking and walking with braces were compared.

Each subject had between 50 and 70 electrodes functioning at any time. Analysis of 702 electrodes implanted in the six subjects over a period of 29 months showed a probability of electrode failure which decreased exponentially during the first four months, and then continued constant at two to three percent per month thereafter. Selected failed electrodes were examined with scanning electron microscopy; failures due to manufacturing defects and to fatigue were observed.

With full quadriceps stimulation, the knee extension maximum force was 80 percent of normal while hip muscle (gluteal and hamstrings) forces remained well below normal. With practice patients progressed from using parallel bars to a rolling walker and, in one case, to axillary crutches.

Implantation of the hamstrings, gluteals, and soleus (in addition to the hip flexors, knee extensors, and dorsiflexors) allowed better posture control and improved quality and speed of the gait. Measurements carried out on one subject showed a 40 percent increase in stride length (from .7 m to 1 m), 2.5 times increase in speed of walking (from .16 m/sec to .4 m/sec, over a distance of 15 m), a decrease in time of double support (from 1.24 sec to .58 sec) and less use of the walker for support. Another subject's walking speed increased from .1 m/sec to .48 m/sec, and the stride length increased from .64 to 1.4 m.

Closed-loop control for standing was introduced in the laboratory computer system with the plantar flexors providing extension moments at the knee for small corrections of the knee and ankle angles and the quadriceps making the larger corrections. The Proportional-Integral-Derivative controllers used, one for each knee and ankle, allowed good standing quality and excellent disturbance resistance for periods of 5 to 10 minutes.

Taking account of the relative muscle masses functioning during FES walking and long-leg brace walking, we found the energy efficiency of FES walking to be comparable with that of brace walking.

Future Plans — Work is directed toward: 1) continued improvement in electrode design and implementation; 2) development of a new stimulator with a larger memory to allow programming of additional functions and to provide interpulse interval modulation of stimuli to increase the response of muscle; 3) development of adaptive controllers to obtain longer duration standing and to provide closed-loop control for walking; 4) evaluation of sensor needs and design of those necessary for the closed-loop system; and 5) development of an improved muscle model.

Sensory Nerve Stimulation for Improved Neuromuscular Control

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Progress — The influence of electrical stimulation of sensory nerve (SNS) upon motor unit control has been investigated in 17 young adult control subjects and 12 subjects with spastic lower extremity paresis. Tonic 20 Hz–0.1 m/sec stimulation of sural nerve at the ankle at levels producing non-painful paresthesias or a sense of pressure over the side of the foot was applied while subjects attempted to maintain constant minimal dorsiflexion of the foot just sufficient for activation of a single motor unit in the absence of EMG or force feedback. Most normal and abnormal subjects feel compelled to increase effort. Some lose awareness of the level of effort and stop dorsiflexion. Usually, proprioception is altered by SNS, the net effect of which is an increase in the force of dorsiflexion. In patients with spasticity, SNS decreases resistance to passive movement at the knee and ankle.

In patients with spastic para- or hemiparesis SNS can improve gait if SNS elicits a strong flexion reflex and the patient is able to stand. Peroneal sensory stimulation is more convenient than sural nerve stimulation. Stimulus intensity was adjusted to produce paresthesias but no motor response. Tonic bilateral stimulation can be used. Heel-toe walking was improved and did not require alternating stimulation of each leg. In some patients SNS was found to enhance the first inhibitory phase of the H-reflex excitability cycle at 70 m/sec. Thusfar six patients have been evaluated using peroneal sensory nerve stimulation. Each has used the stimulator daily for at least six weeks. The technique has proved to be a useful aid to ambulation.

I. Functional Electrical Stimulation

4. Other

Predictive Factors for Restrengthening Paralyzed Muscle by Electrical Stimulation

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Sponsor: Paralyzed Veterans of America

Purpose — Electrical stimulation of paralyzed muscle could be potentially useful for many persons with spinal cord injuries, however little work has been done to document this assumption. Furthermore, electrical stimulation is not presently being used on a large scale for persons with spinal cord injuries because physicians cannot predict how various patients will respond to electrical stimulation. The goal of this project is to develop a set of tests that will help physicians to predict the responses of muscles to electrical stimulation.

Progress — We have begun preliminary studies on determining predictive factors with 18 patients of the Hines VA Spinal Cord Injury Service. All patients have given their informed consent to the research protocol. This predominantly male population provides a diverse mix in terms of level and completeness of injury,

actual age and years post-injury, height and weight, and medical and psychological complications brought on as a result of spinal injury. We have not considered individuals with damage to their spinal cord below T11, with severe peripheral vascular or cardiovascular problems or with presssure sores in areas affected by stimulation, for this protocol.

We completed initial evaluations on these patients using electomyographic, radiographic (CT scan), and neuromuscular techniques, before entering them in a 4-to-8 week protocol. In this protocol we are stimulating their thigh muscles twice daily during 20-minute exercise sessions, tracking changes in thigh muscle force and fatigue characteristics from week to week. Preliminary results suggest a possible correlation between muscle mass (as determined by CT scan) and initial response to electrical stimulation.

Spasticity Suppression with High Frequency Electrical Stimulation

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Purpose — Current procedures to alleviate spasticity in stroke, cerebral palsy, and head and spinal trauma patients consist of muscle release or neurotomy. These procedures are not reversible or of pharmaceutical intervention, which may cause overall activity suppression and addiction if long-term therapy is administered.

Progress — To circumvent such side effects, we investigated the use of high frequency electrical stimulation as a reversible means of suppressing undesired motor activity.

The studies conducted last year showed that at stimulus pulse rate of 600 or 900 per second, the lowest pulse amplitude and duration are required. Further investigations showed that induced muscle force is suppressed most likely by reversible depletion of ACh in the neuromuscular junction but not by localized nerve membrane block at the stimulus electrode site. The blockade was shown to last effectively over two hours with full reversal of force on stimulus removal.

Electrical Stimulation in Treatment of Scoliosis (Human, Cats, Sheep)

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Sponsor: National Institutes of Health

Purpose — The goal of this project is to develop a method of treating idiopathic adolescent scoliosis by effecting corrective forces through percutaneous electrical stimulation of muscle. In order to achieve this end, we propose to: 1) determine the appropriate muscles to be stimulated and the appropriate stimulation time period by measuring over a 24-hour period the imbalance in EMG activity of muscles which are believed to be involved in spinal curvature; 2) evaluate the long-term effects of electrical stimulation on the force production capabilities of muscle subjected to conditions which would be encountered in the patient; and finally, 3) implement a stimulation system in a pilot study involving approximately five patients using knowledge gained from the above.

Fitness Improvements and Physiological Responses to FES Exercise

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Purpose — The physical fitness of individuals with lower limb paralysis tends to deteriorate because of insufficient or inappropriate exercise. Upper body exercise training has been the primary means to enhance fitness. However, the paralyzed lower limbs tend to waste away because of disuse muscle atrophy and bone demineralization. Functional electrical stimulation (FES) of paralyzed leg muscles can provide a means to improve the integrity of the lower limbs. Therefore, it seems feasible that training regimes which include both voluntary arm exercise and FES leg exercise (performed separately and simultaneously) could enable higher levels of physical fitness to be attained by paralyzed patients.

The goals of the present research project are: 1) to evaluate the effectiveness of exercise protocols incorporating FES of paralyzed muscles for their potential in improving muscle strength and endurance, and general physiologic fitness; and 2) to evaluate the effectiveness of exercise protocols that incorporate simultaneous combinations of FES induced leg exercise and voluntary arm exercise for improving aerobic (cardiopulmonary) fitness.

Progress — FES exercise of paralyzed leg muscles is accomplished by using closed-loop electrical stimulator systems that incorporate either digital or analog circuitry. To date, knee extension exercise via stimulation of the quadriceps muscle groups with surface electrodes has provided the best results. Voluntary arm exercise is accomplished on a combination arm crank-wheelchair ergometer which had been previously designed and constructed.

Several studies have been performed using these exercise systems. The first was related to the development of standardized FES exercise protocols to provide safe and effective means of evaluating performance and to enhance the capacity of the paralyzed muscles for this form of exercise. We found marked improvements in muscle strength and endurance using a progressive intensity protocol where the load weights were gradually increased over a several week period. No known damage to the muscles, bones, or skin had occurred.

Preliminary Results — In evaluating physiologic responses to progressive intensity FES knee extension exercise, there were linear increases in oxygen uptake (VO_2) and pulmonary ventilation (VE). However, heart rate (HR) did not increase above the rest value. The maximal VO_2 achieved (20 pounds load) was less than two times the rest value. These relatively low maximal VO_2 and VE values and the lack of HR response cast doubt as to the ability of this exercise mode to provide much of a cardiopulmonary training effect.

It seems possible that the inability to perform FES exercise at higher levels is in part due to inadequate cardiovascular system adjustments. Insufficient blood flow to and from the exercising muscles would lead to the early onset of fatigue. Required adjustments (e.g., increased cardiac output and redistribution of blood from inactive tissues to the active skeletal muscles) are normally mediated through autonomic sympathetic stimulation. However, FES exercise is peripherally induced (which in effect bypasses the central nervous system), and many patients with impaired neuromuscular function (e.g., spinal cord injured) also have impaired autonomic function.

Another concern is the low efficiency that we found for spinal cord injured subjects performing FES knee extension exercise in comparison to able-bodied individuals performing the same task voluntarily. Indeed, the VO_2 during FES of the paralyzed muscles at 20 pounds load was similar to that for the voluntary exercise at 40 pounds load. This inefficiency may be due to histochemical characteristics of the paralyzed muscles, inappropriate stimulation patterns, and stimulation of inappropriate muscle fibers.

The most recent study incorporated spinal cord injured subjects performing maximal effort voluntary arm crank ergometry (ACE) and FES knee extension exercise separately and simultaneously. We found additive VO_2 and VE responses during the hybrid FES-ACE exercise, whereas the marked increase in HR was completely an effect of the voluntary ACE exercise. Knee extension performance as indicated by resistance to fatigue was significantly better during hybrid FES-ACE exercise than during FES alone. This may be due to enhanced sympathetic stimulation induced by the voluntary ACE exercise. These findings suggest that hybrid FES-ACE exercise may be used to increase active muscle mass and the maximal VO_2 achieved. This may improve the training capability of paralyzed individuals.

Future Plans — Future studies will include further development of FES exercise and hybrid FES-ACE exercise protocols to improve muscular and cardiopulmonary fitness. In addition, physiologic evaluations will be aimed at providing a better understanding of the limiting factors for FES exercise. Therefore, studies involving the determinations of central hemodynamic responses (e.g., stroke volume and cardiac output) and peripheral blood flow to the exercising muscles are being planned.

Electrical Stimulation of Paralyzed Muscle After Spinal Injury

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Purpose — Individuals with spinal cord injury have absent or diminished control over muscles that are innervated below the level of their injury. Many of these paralyzed muscles can be activated by electrical stimulation of the nerves leading to these muscles.

Progress — This study attempts to identify the therapeutic benefits of a regular program of electrically-induced leg reconditioning and exercise in a general population of veterans whose legs have been paralyzed by spinal cord injury. The study group consists of individuals with paraplegia and quadriplegia who are patients of the Spinal Cord Injury Service of the Veterans Administration Hospital at Hines, IL. This predominantly male population provides a diverse mix in terms of level and completeness of injury; actual age and years post-injury; height and weight; and the extent of cardiovascular, renal, urinary, skeletal, neuromuscular, peripheral vascular, cutaneous, and psychological complications brought on as a result of spinal injury. We did not consider individuals with damage to their spinal cord below T11, with severe peripheral vascular or cardiovascular problems, or with pressure sores in areas affected by stimulation for this protocol. To date, we

have completed baseline evaluations on 21 qualifying individuals. We screen an average of three or four additional potential candidates each month. For the most part, the qualifying individuals had incomplete quadriplegia (n = 10) or complete paraplegia at T11 or above (n = 7).

For this study we first measured torque and fatigue characteristics produced by an 100 ma stimulus (a 20 Hz train of 0.5 msec compensated monophasic pulses) delivered to the knee extensors via large (2 × 4cm) water soaked surface electrodes in alternating fashion (2.5 sec ON, 2.5 sec OFF). We then placed 18 of the individuals in a twice-daily, 6-day-a-week, 20-minute exercise protocol, with weekly assessments of progress. After four to eight weeks of electrically-induced exercise, some participants exhibited large increases in muscle force and fatigue-resistance while others showed little change. We are now attempting to correlate the extent of increases seen (if any) with our other observations.

Skeletal Muscle Adaptation to Electrical Stimulation: Rehabilitation of Fast and Slow Skeletal Muscle

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — We hypothesize that the functional electrical stimulaton (FES) protocol necessary for optimal muscle strengthening depends on the fiber type distribution within the muscle. Specifically, stimulation parameters used (frequency and duty cycle) may differentially affect fast and slow muscle fibers. Thus, it may be necessary to tailor a stimulation protocol to the fiber type distribution within the muscle.

Progress — Specific questions to be answered by this study are:

1) Does FES of skeletal muscle during immobilization prevent the atrophy observed with immobilization alone?

2) Does high frequency stimulation strengthen immobilized muscle to a greater extent than low frequency stimulation?

3) Do fast muscle fibers respond differently to high versus low frequency stimulation (same question for slow fibers)?

4) Does FES strengthen atrophied muscle to the same extent as normal ambulation?

5) Does FES strengthen a previously atrophied muscle to the same extent as it does a muscle undergoing atrophy, i.e., is it necessary to apply FES during the atrophic process or can it be applied later with the same results?

In order to address these questions, an animal model has been developed. Tibialis anterior and soleus muscles of New Zealand white rabbits are cast-immobilized and then activated for one hour/day × five days/week × four weeks. Following the stimulation treatment, contractile and morphometric properties of the muscle are measured.

Preliminary Results — Preliminary studies indicate that immobilized ankle position and stimulation frequency both significantly affect muscle strength and type S (slow) muscle fiber size. Further studies are underway to determine optimal stimulation protocol as well as FES efficacy in treating disuse atrophy.

Functional Electrical Stimulation for the Prevention of Pressure Sores

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — A new methodology for preventing pressure sores is under investigation that employs functional electrical stimulation (FES). A number of mechanisms have been identified through which FES can help prevent pressure sores. These include both immediate/dynamic and chronic effects of muscle stimulation. The immediate/dynamic effects include tissue undulation and increased blood flow. Chronic effects include increased strength and bulk of atrophied muscle, increased vascularization, and alteration of other tissue parameters.

Progress — Initial studies have focused on immediate/dynamic effects. Appreciable changes in seating interface pressures (greater than 20mm hg.) have been produced in able-bodied subjects using low stimulation levels (less than 50 percent of maximum). Ultrasonic imaging has verified that significant alteration of buttock shape and configuration are associated with these pressure alterations. Continuing research plans call for radioactive tracer studies to quantify stimulation effects on blood flow and clinical trials to evaluate both immediate and chronic effects of muscle stimulation.

Skeletal Muscle Adaptation to Electrical Stimulation: Specific Tension of Isolated Fast and Slow Muscle Fibers

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Long-term chronic stimulation of skeletal muscle causes conversion of fast muscle to slow muscle. This conversion takes place at the level of the single muscle fiber. It is therefore probable that much skeletal muscle which is stimulated therapeutically undergoes a fast-to-slow fiber type conversion. While slow muscle fibers can generate force for a longer period of time than fast fibers, the intrinsic strength of the two muscle fiber types is not known. Data obtained indirectly from studies of single motor units suggest that type S (slow) motor units generate less force per unit area than type FF or type FR (fast) motor units. Thus, fast-to-slow fiber type transformation secondary to FES may actually weaken muscle.

The purpose of this project is to directly measure the specific tension (i.e., intrinsic strength) of isolated fast and slow muscle fibers. Fibers are dissected from the tibialis anterior muscle of the leopard frog (*Rana pipiens*). Contractile and structural properties are monitored using the technique of laser diffraction.

Progress — Preliminary studies have demonstrated that the sarcomere behavior along the length of fast muscle fibers is very complex. Specifically, for a given muscle fiber undergoing a fixed-end contraction, fiber force developed may vary by as much as 50 percent depending on the relative movement of the different populations of sarcomeres along the fiber length. Generally, end-region sarcomeres shorten while center-region sarcomeres lengthen during the fixed-end contraction. In the slow muscle fibers, this type of divergent behavior does not occur.

V. Functional Assessment

[See also pgs. 9, 35, 132]

Improved Methods of Quantification of Function/Performance

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Sponsor: National Institute of Handicapped Research

Purpose — The University of Texas at Arlington (UTA), the Dallas Rehabilitation Institute (DRI), the University of Texas Health Science Center at Dallas (UTHSCD), and the Dallas Rehabilitation Foundation (DRF) have formed a research consortium that established the Center for Advanced Rehabilitation Engineering (CARE). The primary research goal is to develop improved methods for quantification of sensory and motor function in handicapped individuals. Central to this effort is the computer-automated laboratory system for quantitative assessment developed in the joint UTA/UTHSCD Biomedical Engineering Program. The system includes measurements of mental alertness, vision, hearing, speech, steadiness, reactions, tactile sensations, manual dexterity, range of motion, speed and coordination, postural stability and control, selected activities of daily living, strength, resistance of passive motion, and fatigue. The laboratory is being expanded to include assessments of gait and proprioception as well as some of the above functions at new body sites. New instruments and software are being developed, and the system's reliability and utility for assessing the function of handicapped individuals are being evaluated.

Development of a Computer-Automated System for Functional Assessment

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Purpose — Researchers at UTA have developed a computer-automated system to quantitatively assess a broad selection of sensory and motor functions. The objectives of this project are to further develop and expand the basic system and to prepare two complete prototype systems for clinical evaluation and application studies at our clinical settings, the University of Texas Health Science Center at Dallas (UTHSCD) and the Dallas Rehabilitation Institute (DRI). In this battery of tests each function is assessed by having the test subject carry out very specific simple and short duration tasks that usually involve responding to computer-generated stimuli. Special purpose transducer modules have been designed to convert responses into voltages for digitization by computer. Signal processing algorithms compute single number results for most tests that quantitatively indicate the level of a specific function.

Progress — Clinical evaluation sites at UTHSCD and DRI have been established. Each is equipped with a basic version of the computer-automated sensory and motor function test battery. Patient and normal data are being collected routinely to meet the objectives of planned studies. An automated database management

system with interactive test result inspection capabilities has been implemented. At present, the database contains more than 1500 records of sensory and motor function, of which approximately one-half represents patients with various handicaps. The other half represents normal data that are essential to interpret patient findings properly. It is possible, through a computerized process, to collect any or all of 150 measures of sensory and motor function, deposit results in the database, and examine an individual's results by comparison to a selected subset of the normal population. Results are expressed in terms of standard deviations from the selected comparison population. Cooperative research that allows replications of the system to be used and evaluated at external sites has been entered into with Chicago Shriner's Hospital and Cordis Corporation. Similar efforts at other sites are pending.

New devices and software have been completed recently for measurement of: 1) forearm pronation/supination speed, strength, and range of motion; 2) speech motor function; 3) resistance to passive motion (rigidity/spasticity) and isokinetic strength (separate devices for finger/wrist, knee/elbow, and ankle); 4) range of motion about most body joints; and 5) spinal curvatures.

Software for personal computers has been developed to allow interface to the database and display of individual results as well as test/retest comparisons in various easy to interpret forms, such as graphical profiles of anatomy and corresponding color-coded levels of relevant sensory and motor functions at each site. Expert systems are being developed to provide more refined information to individuals in various disciplines that may use the system such as neurologists, orthopedists, physical therapists, occupational therapists, and vocational experts.

Skill Evaluator and Trainer

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Sponsor: Channel 10 Children's Medical Research Foundation of S.A., Inc.

Purpose — A device has been developed that objectively evaluates a disabled person's skill in controlling switches, joysticks, and other interfaces to electrical devices and subsequently trains the disabled person to use the interface which is best suited to his capabilities. The need for such a device has been established, and its reliability and validity have been authenticated. Negotiations for its commercial production are in hand.

Quantitative Measures for Assessing Gait

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Sponsor: National Institute of Handicapped Research

Purpose — The objective of this project is to develop an easy to use multi-dimensional parameter technique that can characterize significant abnormalities in gait. The parameters will be used to assess the effectiveness of various types of therapeutic interventions. Normals are currently being run to obtain a standard database.

Clinical Evaluation and Application of a Computer-Automated System for Functional Assessment—Part I

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Sponsor: National Institute of Handicapped Research

Purpose — A prototype of the Center's computer-automated quantitative assessment system is being evaluated for test/retest repeatability, effects of age, gender, and handedness while gathering normal sensory and motor function data and short- and long-term stability of patient data. Other studies involving rehabilitation of knee injured patients, postoperative spinal pain patients, spasmodic dysphonia, and post-polio subjects are being carried out in cooperation with local investigators.

Progress — Significant progress has been made in evaluating carefully screened normal individuals to establish a sensory and motor function database. To date, norms for approximately 150 measures have been obtained. Test/retest data are being used in a large scale study of reliability and learning effects. Results obtained for eight tremor measures and 14 strength measures indicate good repeatability and little or no learning effects.

Patients with progressive neurologic diseases such as Parkinson disease, multiple sclerosis, myasthenia gravis, Huntington's disease, and chronic low back pain and those receiving neuroleptic medications also are being characterized. These studies are planned to continue and will be expanded as new tests move from development to clinical stages. The total number of measures that can be selected is expected to grow to 350. These tasks are facilitated by the automated nature of the system and database. The majority of these measures can be obtained in a two-hour test session. However, in routine use only selected subsets of available tests would be administered.

Clinical Evaluation and Application of a Computer-Automated System for Functional Assessment—Part II

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Sponsor: National Institute of Handicapped Research

Purpose — A second prototype of the Center's computer-automated quantitative assessment system is being evaluated clinically and used to conduct studies at The Dallas Rehabilitation Institute (DRI). Work at this site has been underway to evaluate the sensory and motor function of patients with head injuries, spinal cord injuries and peripheral neuromuscular damage, cerebral palsy, amputated limbs, spinal pain, and arthritis. Data are being used to develop functional profiles and databases of these conditions, as well as to document effects of therapy and recovery trends. At this time, 152 patients have been evaluated in 218 test sessions.

Progress — DRI investigators have closely collaborated with those at UTA and UTHSCD to improve test devices. As experience with these patient groups increased, several modifications to test devices were found necessary. A project is in progress to compare data acquired at the UTHSCD clinical site to data on the same set of normal subjects evaluated at DRI. Results will be used to assess factors such as instrument calibration and effects of test administrator training.

Preliminary Results — In one preliminary study fifteen head-injured patients with similar prognoses and at various stages post-injury were evaluated over a broad set of functions. Results indicated that the test battery was effective in documenting function in this population. Results generally improved with time since injury. Short-term repeat testing indicated that stable data could be obtained for most functions, and long-term repeat testing quantitatively documented changes that agreed with other subjective clinical indicators. Short-term memory and upper and lower extremity strength were shown to be least impaired, while activities of daily living, manual dexterity, and upper and lower extremity reactions, speed, and coordination showed the greatest losses. The average function of the group across all measures ranged from one to four standard deviation units below that of norms of similar age and gender. An expanded study is underway.

Measurement of Muscle Strength, Endurance, and Range of Motion

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Sponsor: National Institute of Handicapped Research

Purpose — The goal of this project is to develop a computerized isometric muscle strength, endurance, and range of motion measurement system. The unique aspect of the system is its ability to quickly and easily make measurements on the entire body from the neck down to the ankle. The system will use a special joint stabilizing chair and table with multiple load cells in order to make measurements from 24 muscle groups on each side of the body.

Progress — The data are collected using an Apple computer with an analog to digital converter. The delay time, rise time, and the decay of the force response are calculated. The EMG is measured and parameters relating to the timing of the EMG with respect to the force response are calculated along with frequency shift information related to fatigue.

The computer software has been completed and the first prototype chair is undergoing testing.

Quantification Mobility Performance for Functional Assessment, Diagnosis and Therapy of Neuromuscular, Skeletal, and Synovial Joint Dysfunctions

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Sponsor: National Institute of Handicapped Research

Purpose — This comprehensive computer-based project, first described in the 1983 Veterans Administration Rehabilitation Research and Development Progress Reports, will provide the orthopaedic surgeon with a computer-assist similar to that which the engineer enjoys with Computer-Aided Design (CAD). With CAD the engineer may plan orthopaedic procedures on a computer display of the patient's anatomy and then view on an animated computer screen a simulation of the consequence of the procedure on the patient's posture and gait, with the opportunity to iterate and improve the procedure before undertaking actual surgery. Enhanced confidence in outcome, including the likelihood in some situations of the choice of non-intervention, and quantitative assessment of

change are the expected utilities of Computer-Aided Surgical Simulation (CASS). The overall project is comprised of several components and is relevant to functional assessment in its own right.

Progress — Regarding gait analysis, our Selspot I/TRACK system at MIT has been augmented by our Selspot II/TRACK System with improvements in kinematic resolution and accuracy and greater flexibility. The necessary frequency or sampling requirements for adequate kinematic data in human gait have been reported. Graduates of our program have installed a 4-camera, 2-forceplate Selspot II/TRACK System at the Massachusetts General Hospital for orthopaedic/pediatric movement analysis.

With reference to dynamic joint force estimation, our NEWTON computer program automatically calculates joint forces and moments using TRACK kinematic data, forceplate input and body segment mass, and inertial properties. The latter constitutes the greatest uncertainty in dynamic calculations since all methods described in the literature are based on very small and non-representative cadaver samples. We have developed computer programs that automatically calculate the patient-specific inertial tensor using as input computer tomographic or magnetic reasonance imaging data. Physical experiments on cadaver limb segments to compare direct measurement of the inertial tensor with our tomography-based computer analyses are underway.

Preliminary Results — We now have a year of data from the first pressure instrumented femoral head hemiarthrosis. Local pressures correlate well with the high and non-uniform readings we have recorded *in vitro* on cadaver specimens. We are attempting to spatially integrate the multiple pressure readings to calculate the direct force vector across the hip joint. Such an internal measurement would augment the dynamic joint force estimation from kinematic and force plate measurements and permit evaluation of the role of muscle co-contraction.

TRACK data into NEWTON followed by optimization analyses predict the force versus time of each of the 36 mono- and bi-articular muscles of the pelvis, thigh, shank, and foot complex. To improve the knee representation of our leg model, we are generating an explicit mathematical description based on experimental measurements and using our ultrasound technique for the articular and menisci geometries and incorporating the passive restraints of the ligaments. Reduction and interpretation of data on knee kinematics for which TRACK arrays were mounted on bone-pins disproves the contemporary crossed four-bar linkage model of the knee function, and demonstrates four degrees of freedom. When inserted into our overall leg model, including the 15 muscles that span the knee, the new knee representation will have four degrees of freedom and will improve the accuracy of prediction of individual muscle activity.

The surgeon must be presented with a realistic, manipulable representation of the subject's anatomy as she/he undertakes simulated surgery. The same data used for segment inertial property determination serve also as input to the anatomical representation. Automatic feature detection delineating between hard and soft tissue has been demonstrated, as has a data compression approach, based on frequency domain analysis, which achieves an order of magnitude in computer memory requirements.

Computer vector graphics displays of patients movement preoperatively and subsequent to a simulated operation must also be as realistic as feasible. Current stick-figure representations do not include segment orientation data and cannot capture nuances of pathological and/or idiosyncratic movement. We have developed computer programs that represent the limb segments as articulated solid bodies, which when driven by TRACK kinematic data produce much more adequate displays of human movement.

Predictive Assessment in Prescription of Functional Aids for the Motor-Disabled

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Sponsor: National Institute of
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Purpose — The goal of this project is to develop data and theory on which to base prediction of functional gain from technological intervention. It was proposed that this concept be applied to three handicapping conditions: 1) disabling tremor of the upper extremities; 2) "equinus" and other spastic gait abnormalities; and 3) loss of vocal communication due to impaired articulatory motor control.

Progress — Work in the area of computer-guided assessment for prescription of non-vocal communication devices has continued, demonstrating accurate prediction from objective assessment data of communication rate using non-vocal communication devices. Straightforward phenomenological models of the dependence of movement time on distance, angle, and target size account for a major part of the performance differences observed among assessment tasks. Models derived in this way will provide a sound basis for device-specific rate predictions as part of a clinical selection scheme.

The primary area of work in this REC project since the last Progress Report has been in the area of spastic gait. Advances have been made in two directions—continued technical development of the laboratory-based wearable orthosis simulator and ADL testing of a prototype practical damping orthosis. The simulator applies energy-absorbing loads by means of a magnetic particle brake. Resistive torque is controlled in real time by a DEC 11/60 computer on the basis of signals from angle and force sensors as well as sole switches. Final preparations are complete for synchronous data acquisition from the simulator and the Laboratory's Selspot-based TRACK system, and real-time brake control.

The ADL prototype orthosis based on a passive linear damper was used at home by a cerebral palsied child for six weeks. Anecdotal data gathered by his highly cooperative family demonstrated gradual improvement in the range of activities (walking, running, stair-climbing, and jumping) in which the subject felt comfortable wearing the brace. An apparent subject improvement in gait was observed by his family. This was corroborated in the laboratory by means of weekly TRACK measurements. Analysis of kinematic data revealed that wearing the brace caused statistically significant reduction of mid-stance plantar flexion and reduction in the angular velocity of ankle dorsiflexion normalized by gait velocity during roll-over. It also confirmed (for this subject) the hypothesis that the abnormal reflex plantar flexion is triggered by dorsiflexion velocities above a threshold value. Redesign of the ADL orthosis for improved cosmetic and fit is planned.

VI. Biomechanics

A. Joint Studies

1. General

Vibration Studies of Bones and Joints

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The objective of the two research projects underway is to develop techniques for early diagnosis of joint and bone disorders by studying their vibration characteristics.

Progress — The proposed protocol will characterize vibration analysis including system identification techniques. The following two studies will be performed and correlated:

1) *Knee joint study*. The testing procedure will consist essentially of measuring the acceleration and acoustic emission output from knee joints while they are in active articulation. The tests will be carried out on a sufficiently large number of subjects representing a wide variety of possible joint conditions, e.g., normal, rheumatoid arthritis, degenerative joint disease, etc. Moreover, joint conditions in different stages of severity will be studied. The data will then be processed to evaluate the sensitivity of the technique to the extent or severity of the condition and the sensitivity of the measuring technique to different types of joint abnormality. The equipment and the measuring technique also will be evaluated for convenience in the event of general clinical application. The effect of age, weight, sex, and any other relevant parameters will be examined.

2) *Bone vibration study*. The first part will be to obtain the natural frequencies, damping, and mode shapes of bones *in vitro* by using different methods of excitation, such as hammer impact or shaker excitation. The second part will consist of using these measurements as inputs to an analytical structural dynamic system identification procedure to obtain distributions of physical properties of the bone, such as mass, damping, and stiffness. The *in vitro* measurements will be verified against actual measured properties. If the *in vitro* tests prove successful the *in vivo* test procedure will be developed. Preliminary *in vivo* tests have been done and they are noninvasive and non-traumatic. Sensitivity to the type and severity of the bone disease will be evaluated.

Preliminary Results — During the first 30 days of this project, the investigators assembled the equipment necessary for the proposed work.

Control of Metrical and Timing Precision in Human Movement

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Sponsor: National Institutes of Health

Purpose — This study proposes to investigate central nervous system control strategies used to produce accurate movements. Control of voluntary movement is viewed in this study as a stratified process with several levels of control: 1) movements are initiated by high level construction of open-loop motor commands, which are 2) executed from a reference frame stabilized by a postural control system, and are 3) modified by sensory feedback during both command execution ("concurrent feedback") and after movement completion using knowledge of results ("delayed feedback"). Skilled movements and isometric force production are evaluated in terms of these three control mechanisms.

Progress — Adult, human subjects will track various waveforms presented on a visual display by exerting force on a manipulandum with their elbow musculature. Comparison will be made of motor accuracy under a variety of conditions affecting: 1) the predictability of the stimulus (tracking waveform) amplitude; 2) the availability of visual feedback; 3) the degree of postural stability; and 4) movement of the elbow joint. In most experiments subjects will track step waveforms on an oscilloscope screen while, in one experiment, designed to distinguish between strategies subserving timing and metrical movement precision, graphical displays will be more complex. Electromyographic activity will be recorded from appropriate muscles during tracking experiments in order to characterize movement strategies at a level of peripheral neural commands to muscles.

Amputees fitted with myoelectrically controlled arm prostheses will be used in several phases of this study. In one experiment, these individuals will be used as a model of the "deafferented arm" in order to characterize this role of peripheral somesthetic feedback in the control of accurate movements in normal subjects. In addition, a pilot experiment is proposed which directly addresses the problem of user control of multiple degree-of-freedom powered arms. It is hoped that the latter experiment will lead to the development of a large-scale research and training program for amputees at Good Samaritan Hospital and Medical Center.

Biomechanics of Bone Resorption/Regeneration at a Bone Implant Interface

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The objective of this work is to clarify understanding of bone remodeling in relation to the biomechanical conditions at an implant-bone interface as a step toward quantitation of "Wolff's Law" as it pertains to implants. Research will attack the problem with the aid of a model involving both trabecular and cortical bone of dogs. Via specially shaped stress devices and controlled application of loads, interfacial bone will be subjected to known states of stress for a one-week-period, to be followed by analysis of interfacial bone activity in response to the dynamic mechanical environment.

Progress — The stress devices (which resemble screw-type dental implants) are implanted into trabecular bone of dog mandibles, and cortical bone of dog radii,

and remain load free for 3 months. Programmed loads then are applied to the stress devices by a computer controlled loading device, and interfacila mechanics calculated by finite element stress analyses. Bone activity is documented by tetracycline labeling and related histomorphometry.

Preliminary Results — Loading regimes have been completed on six loaded and six control screw implants in beagle radii as well as on six T-shaped mandibular implants in six other dogs. Undecalcified bone sectioning has been completed on all tissue specimens and histomorphometric analysis of results is currently in progress using both normal light as well as fluorochrome techniques. Results are to be completed within the final year. Three-D finite element analysis of stress on the implants has highlighted interfacial bonding as a major factor in stress prediction but further work will be required to define the status of this factor in our experimental model.

Stimulation of Repair of Cortical Bone Transplants by Implantation of Piezoelectric Materials: Development Study

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Our purpose is to develop a new approach to electrical stimulation of bone healing based on design of a less-rigid internal fixation plate incorporating a piezoelectric material to generate electric currents during physiologic loading. We are evaluating two approaches to design of internal fixation plates incorporating piezoelectric materials. In Type I, a piezoelectric ceramic or polymer is attached to the underside of the plate and is in direct contact with bone. In Type II, a piezoelectric ceramic is sealed within the plate; the current output is delivered to bone by electrodes.

Progress — Tests have been conducted with both designs using miniature piezoelectric internal fixation plates ($36 \times 6 \times 1.5$ mm) attached to beagle radius, ulna and femur. Effects of the Type I plates have been studied by histological observations on drill holes or osteotomies beneath the active piezoelectric surface. Type II plates have been studied by measuring output during *in vitro* loading, and during actual walking *in vivo* using beagles. Output also has been measured during excitation with external ultrasound.

Tests of Type I plates have failed to demonstrate any direct action of piezoelectric materials on bone formation. Tests with Type II plates have been successful in generating significant currents *in vivo*. In beagles, following rectification of plate output, average direct currents of 0.2-0.4uA have been generated during walking and currents exceeding 50uA have been generated by external ultrasonic energy ($10 mw/cm^2$) applied to the skin.

Tests of piezoelectrically generated currents on bone formation in rabbits are in progress as are design studies on larger (human scale, Type II) piezoelectric plates for tests in large animals. This new type of orthopaedic implant could add an important resource in prevention and treatment of non-union.

A. Joint Studies

2. Lower Limb

Clinical Biomechanics of the Knee-Rotatory Laxities

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Sponsor: National Institutes of Health

Progress — Much controversy exists over the significance of the knee laxity exam. This has resulted, in part, from a lack of knowledge of the restraining functions of the various ligaments and capsular structures. During the first grant period, we measured the ligament restraints to the so-called "straight instabilities." These instabilities are the anterior-posterior drawer and the straight medial-lateral opening. In the proposed renewal period, we will study the restraining action of the ligaments to the rotatory instabilities. These instabilities involve combined rotational and translational knee motion. The rotary motion is associated with axial tibial rotation. The translations are anterior-posterior drawer and medial-lateral shifting of the tibia.

Future Plans — We propose to address the problem of defining the significance of rotatory laxities with regard to injury by applying three distinct methodologies. They include: 1) measuring the three-dimensional restraining forces of the ligaments to well defined and reproducible rotations of the tibia; 2) measuring the three-dimensional motions which occur during the various clinical exams for rotatory instability along with the changes in motion associated with specific ligament injuries; and 3) synthesizing these results on ligament function into a mathematical model capable of testing our understanding of both the effects of the various individual factors (i.e., ligaments, joint geometry, compressive forces, etc.) and their complex interactions.

Biomechanics of Anterior Cruciate Repairs (Human)

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Sponsor: National Institutes of Health

Purpose — The goal of the proposed research is to better understand the mechanical factors in surgical repair procedures for chronic anterolateral insufficiency of the knee, for which the repair requires an anterior cruciate substitute. Experiments will be run on cadaver knee specimens in which ligament forces will be measured by buckle force transducers on the four major knee ligaments. A six degree-of-freedom goniometer system will be used to measure three-dimensional knee motion when the knee is subjected to a wide variety of external load directions.

Normal knees, knees with a simulated anterolateral injury, and knees repaired by one of eight procedures will be tested in an identical manner. Theoretical ligament lengths and hence, loaded ligament states will be predicted using already-developed theoretical knee models, with the measured 3-D motion as

input. The influence of repair insertion location will be studied both theoretically and experimentally. The normal and repaired knees will be compared on the basis of anterior cruciate or substitute force magnitude, joint laxity, and load sharing by the other ligaments.

Biomechanical Comparison of Total Elbow Replacement Prostheses

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Sponsor: VA Rehabilitation Research and Development Service

Progress — Mechanical design parameters of nine total elbow prostheses (Coonrad II, Pritchard Mark II, Stanmore, Schlein, Triaxial, Mayo, Capitello-Condylar, London, and Wadsworth) have been compared. All implants were "regular" or "medium" sizes. Eight different biomechanical parameters were measured. After studying cadaver specimens, a geometric relationship was identified to assess the ability of each prosthesis to replicate the flexion/extension center of rotation of the normal elbow.

Preliminary Results — A surprisingly wide range of biomechanical parameter limit values were found among the prostheses: (in degrees) flexion: 124 to 180; hyperextension: 0 to 165; internal/external rotation: 0 to 11.8; cubital angle: 0 to 27; varus/valgus: 0 to 11.5; and (in mm) subluxation 0 to 5.6 (for constrained designs), humeral stem length, 68 to 181, ulnar stem length, 24 to 83. The center of rotation offset ranged from less than 1.5 mm to more than 4 mm.

The Stanmore prosthesis was the most constrained design, the Wadsworth provided no cubital angle, and the Mayo and Coonrad II allowed much greater hyperextension than other designs. This relative lack of mechanical constraint in hyperextension might be a problem in patients deficient in ligamentous constraints. The unconstrained designs typically had shorter stems and surface geometries allowing less varus/valgus motion than all the more constrained designs except the Stanmore. These results were submitted in June 1984 to the Orthopedic Research Society and were presented at the annual meeting in January 1985 (*Transactions of the Orthopedic Research Society* 10:100, 1985).

Clinical failure rates due to loosening, and the wide range of design configurations available indicate that a basic general design envelope for elbow prostheses has not yet been established. The available prostheses are either quite unconstrained to prevent loosening and therefore are limited in application, or are substantially constrained and subject to early failure due to forces transmitted from the constraints to the prosthesis/bone interface. To complete this project, a prototype for a new prosthesis was designed, fabricated and subjected to preliminary mechanical evaluation. The principal goal for the prototype was to provide a moderately constrained (and therefore widely applicable) design which would be much less likely to loosen.

Mechanical analysis suggests that both axial and torsional loads at the humeral interface contribute to loosening of constrained designs. In order to minimize these loads, the prototype humeral component was designed with a titanium alloy stem of cylindrical cross-section free to move axially and rotationally in a close-fitting cylindrical hole centered in a polymer sleeve. The external surface of the polymer sleeve was designed to conform to the shape of the humeral canal with

minimal reaming, allowing cementless, press-fit implantation. The polymer sleeve surface geometry was based on sectioning and measurement of 15 middle-age adult cadaver specimens. The sleeve was fabricated from acetal homopolymer to minimize creep and wear. An acetal bushing also was incorporated into the design of the moderately constrained interface between the humeral and ulnar components. The ulnar component was also designed in titanium with a polyethylene-finned peg providing cementless fixation in ulnar trabecular bone.

The prototype prosthetic components were implanted in cadaver specimens. Radiographic evaluation of humeral intramedullary fit was good. Strain gauges placed on the humeral surface near the internal locations of the titanium alloy stem tip did not reveal any marked dicontinuities in bone strain when bending loads were applied to the humerus. Most significantly, simple elbow flexion produced readily visible relative torsional motion between the humeral component's titanium stem and polymer sleeve, suggesting that the design concept may be effective in reducing forces at the prosthesis/bone interface which contribute to loosening.

A detailed description of this work has been published as a Master of Science Thesis (J.C. Serbousek, *Biomechanical Evaluation of Current Elbow Prostheses and Description of a New Design,* Bioengineering Department, University of Utah, June 1985), and manuscripts for journal publication are in preparation.

Mechanical Function of the Repaired Meniscus

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Healing of load-bearing tissue does not necessarily constitute restoration of mechanical function, especially if tissue dimensions or mechanical properties change during healing. The objective of this project is to determine the mechanical function of the injured and repaired meniscus, using the healthy, mature canine stifle joint as a model. The canine menisci have been demonstrated to function similarly to human knee menisci and have a similar vascular supply.

Progress — Forty 23-27 kg mongrel canines have received either a complete transsection or a longitudinal incision unilaterally in the medial meniscus, followed in each case by a standard surgical repair. Six additional animals have been subjected to a sham procedure in which the joint space was violated but the meniscus was not. After being allowed subsequent free movement in individual dog runs, the animals presently are being sacrificed at either 13 or 26 weeks postoperatively.

Several related test protocols have been developed and are being applied for assessment of biomechanical function. Tests are performed on both the operated limb and the unoperated one so that results can be normalized and compared from animal to animal. First, quasi-static joint load/displacement curves and meniscal hoop strain are measured at different joint angles. The loads are applied with an Instron test machine and displacements and strains are measured with resistance strain gauge extensometers. A multi-channel, analog-to-digital data acquisition, conversion and processing system has been developed for collecting these data, displaying load/displacement curves and computing structural stiffness.

Next, the pressure distribution pattern of the meniscus on the tibia as a result of femoral loading is obtained with pressure-sensitive film introduced between the meniscus and the tibia. The load-bearing area is determined on the film with a digitizing pad and associated software developed for bone histomorphometry measurements. Then, the maximum pressure and its point of application are measured with a commercial densitometer designed for use with the pressure-sensitive film.

Finally, the meniscal tissue is excised and its approximate strength and stiffness in tension are determined on another Instron machine. Special fixtures have been developed for gripping the tissue. A histologic assessment of healing also is being performed on the repaired tissues, and articular surfaces adjacent to the repaired menisci are being examined for damage.

Future Plans — It is expected that testing will be completed in the next three months. If meniscal repair can be shown to be biomechanically effective, the hypothesis that such repairs can be expected to minimize post-injury incidence and severity of degenerative arthritis in the knee will be strengthened substantially.

Biomechanics of Hip and Knee (Human)

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Sponsor: National Institutes of Health

Purpose — This research is directed towards the advancement of our understanding of the biomechanics of the hip and knee. The work involves a documentation of hip and knee mechanics in normal subjects, patients with degenerative joint disease, and patients with surgical reconstruction of their joints, during a variety of daily activities. This research specifically involves the development of a three-dimensional model of the lower extremity including origin and insertion points of all muscles about the hip and knee (and selected muscles about the ankle) and origin and insertion points of knee (and ankle) ligaments. This model is utilized in an investigation of various schemes to distribute calculated intersegmental resultant forces and moments about the hip and knee to the actual anatomic structures carrying these loads.

A validation of this distribution investigation is being conducted in normal and pathological situations utilizing EMG recordings. This investigation will finally result in the collection as well as reporting of data on the mechanical function of the hip and knee. This is necessary to rationally design, utilize, and evaluate various treatment modalities.

Biomechanics of Anterior Cruciate Ligament Reconstructions (Dogs)

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Sponsor: National Institutes of Health

Purpose — The biomechanical parameters underlying reconstruction of the anterior cruciate ligament (ACL) of the knee have been incompletely studied. The ACL is frequently totally disrupted in athletic trauma and other accidents. Since the ACL is important in the kinematics of the knee, its correct function is vital in maintaining joint integrity. We will utilize a proven Hall-effect displacement

transducer to measure ligament strain prior to and immediately following ligament reconstruction in canines. The same technique will be used as part of the measure of function after two year's rehabilitation.

At two years, we also will measure the strength of the ligament at the time of sacrifice. We will relate a composite score of function and joint pathology to the biomechanical quality of the original reconstruction. The functional score of the reconstructed and control groups will be compared. Thus, we will establish the importance of the original strain pattern of the ACL as well as clarifying the ability of the reconstruction to mimic the biomechanical functions of the ACL.

In a related study, the protective function of casts, cast braces and other braces commonly used following ACL reconstructions will be compared in human cadavers using the Hall-effect device. Similation of appropriate motion and muscle function (isometric in totally restrictive devices such as casts and locked braces, and limited isotonic activity in partially mobile braces and cast braces) while measuring the ACL strain should allow clarification of the safest means of knee rehabilitation.

Ligamentous Knee Stability-Combined Clinical Loadings (Human)

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Sponsor: National Institutes of Health

Purpose — Ligamentous stability of the knee will be quantified *in vivo* and *in vitro* by direct measurement of force versus displacement responses for anterior-posterior tibial drawer, moment versus rotation responses for varus/valgus angulation of the tibia, and torque versus rotation responses for internal and external rotation of the tibia. The stiffness and laxity data collected will quantify the contributions of knee ligaments to overall stability of the joint, and help to improve the accuracy and interpretation of the clinical knee laxity exam.

Existing test fixtures will be modified to study the complex responses of cadaveric knees to combined loading states on an MTS materials test machine, including the application of tibial-femoral contact force (joint load). The effects of knee ligament section and total knee replacement will be examined with this advanced methodology. The UCLA clinical knee testing apparatus will be modified to include measurement of anteromedial and anterolateral rotatory instabilities. Patients with knee injuries will be tested before and after their surgical reconstructive procedures to permit an objective assessment of their operative results. Patients who have received total knee replacements will undergo selected testing to evaluate the stability of their implants *in situ*.

A portable "field" testing apparatus will be designed and prototypes constructed for use in the UCLA clinics and Sports Medicine Center. These units will expand our data collection capabilities and allow screening studies of varsity athletes prior to the competitive season, in order to study correlations of knee stiffness and laxity with the incidence and severity of knee injury.

A. Joint Studies

3. Upper Limb

Static Force and Stability Analysis of Human Elbow

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Sponsor: National Institutes of Health

Purpose — The renewal project will continue the specific aims of: 1) development of a physiologically equivalent normative model of the elbow joint for force analysis; 2) determination of the muscle and joint forces during various functions; 3) verification of the theoretical results; 4) examination of the relative contribution of individual joint support elements (articular surfaces, ligaments, and capsules) to joint stability; and 5) decomposition of the resultant joint forces and moments into each support element. Data for establishing the normative model will be obtained by biplanar X-ray and direct force measurement methods.

In resolving the indeterminate force analysis problem, the method of introducing additional constraint equations based on physiological and pathological considerations combined with the optimization method will be used. The theoretical results will be verified by both qualitative and quantitative electromyographic studies. The relative contribution of the joint support elements in resisting external load at the joint will be measured by performing load-displacement tests of the intact joint followed by sequential sectioning of individual elements. The joint contact area will be obtained by reversible cartilage staining technique and computerized tomography. The decomposition of the joint load will be achieved analytically. The results of this study can be applied to numerous clinical problems, including the design of total elbow arthroplasty components and diagnosis and treatment of the ever-increasing athletic and traumatic afflictions of the elbow joint.

Biomechanical Study of the Radial Ulnar Carpal Joint (Human)

Andrew K. Palmer
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Sponsor: National Institutes of Health

Purpose — Chronic pain and clicking about the distal radial ulnar and ulnocarpal joint associated with weakness of grip and a subjective sensation of wrist instability are frequently results of a healed Colles fracture. This fracture can be a dislocated or subluxed distal radial ulnar joint, arthritic involvement of the wrist, or more frequently, a seemingly rather insignificant wrist injury. Many surgical and nonsurgical treatments deal with these symptoms without the full knowledge of the cause of the symptoms. This is a direct result of the lack of understanding of anatomic and biomechanical interrelationships of the wrist components in normal and pathological situations.

This research program proposes to further pursue our investigation into the anatomy and function of the ulnar aspect of the wrist. Using the techniques developed in the ongoing Biomechanical Study of the Radial Ulnar Carpal Joint, radioulnar carpal, and intercarpal forces and pressures will be studied in the intact

wrist as well as in surgically altered wrists (e.g. ulnar shortening, distal ulnar resection, distal ulnar Silastic replacement, carpal resections, etc.). The analysis of the effect of these operative procedures on the normal wrist biomechanics would lead to recommendations regarding the efficacy of previously recommended treatment modalities for different wrist problems. Improved treatment protocols for specific pathological conditions of the wrist would be forthcoming based on sound biomechanical principles with predictable long-term results.

Influence of Wrist Pathomechanics on Hand Function (Human)

William F. Blair
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Sponsor: National Institutes of Health

Purpose — The overall objective of this research is to advance our understanding of normal and pathologic wrist mechanics. This includes an understanding of the role that individual wrist components (e.g., carpal bones and wrist ligaments) play in producing normal wrist function, an understanding of the disruption of normal wrist function caused by rheumatoid arthritis, and a better understanding of the mechanics of surgical reconstruction of the joint.

Functional Forces in Normal and Abnormal Fingers (Human)

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Sponsor: National Institutes of Health

Purpose — This project attempts to achieve the following objectives: 1) analyze joint, tendon and capsuloligamentous forces in normal and abnormal fingers and thumbs; 2) study the pathomechanics of the fingers and thumbs and their surgical treatment methods; 3) perform objective functional evaluation of hand patients before and after treatment; and 4) correlate the predicted muscle forces and their EMG measurements.

Progress — Normative models for each finger and the thumb have been established based on a precision biplanar X-ray method using marked cadaver specimens. The optimization technique combined with the permutation method and functional grouping have been adopted for force prediction. Quantitative EMG data on normal subjects have been used to correlate the theoretically estimated results. The cross-sectional technique was found to be ineffective in quantitating capsuloligamentous geometry, and it has been replaced by a stereo-video method using high resolution TV cameras. Collateral ligaments of the MCP joints have been studied with improved results. Modeling of the joint capsuloligamentous structure will be achieved using equipollent force analysis. Cadaver finger and joint specimens will be tested on a MTS machine to determine joint contact points and ligament tension to facilitate mathematical modeling. Three groups of patients are being evaluated using the objective method developed from this project to assess their functional deficits and treatment results. Normal subjects also have been studied to establish the reference database. Hand pathological conditions involving joint deformation and strength loss are being studied. The results will be used to evaluate diagnosis and treatment of alternatives.

Mechanics of Control of Movement of Human Elbow Joint

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Sponsor: National Institutes of Health

Purpose — The role of proprioceptive reflexes during active movement is still a matter of controversy despite decades of study. Arguments have focused on what mechanical variable (e.g., muscle length, force) the central drive tries to control during movement. The proposed research addresses the question of what does the central drive accomplish, i.e., what combination of mechanical variables is found to be regulated in postural states and controlled during active movement. There is support that the variable regulated by proprioceptive reflexes is a simple combination of muscle length and force.

This hypothesis is often referred to as "stiffness regulation." For measurements on a joint, the regulated variable translates into a combination of joint angle and joint torque provided there is no co-contraction of antagonists. However, it is not clear whether the dynamic changes in torque and angle that ensue when a perturbation is imposed on the joint are a reflection of the inertia and damping associated with the joint or reflect, or the speed of response of the regulatory system. The first aim is to identify the regulated variable while the joint angle and torque change dynamically in response to perturbation. The second aim is to determine whether or not the combination of mechanical variables that was found to be regulated in postural states is what is controlled during active movement. The third and fourth aims address questions related to the commonly observed contraction of antagonist muscles when the need for such contraction is not apparent. Specifically, what external conditions are sufficient to elicit contraction of antagonists and how is the electromyographic stretch reflex of the antagonists affected? Answers would provide an understanding of the role of proprioceptive reflexes in the control of movement by healthy subjects. Such an understanding is a necessary prerequisite for delineation of the role these reflexes play in pathological conditions characterized by movement disorders.

B. Spine

Mathematical Modeling of the Human Spine: Implications to the Orthotic Management of Spinal Deformities

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Mild to moderate curvatures of the spine are most often treated conservatively using an orthosis such as the Milwaukee brace or the Wilmington jacket. The mechanics of curve progression is of considerable interest to the clinician due to its implications to patient selection for the orthotic treatment as well as the choice of an orthosis.

The purpose of this study is to investigate the stability of a scoliotic curve with and without bracing as a function of the degree of initial curvature (at the time of orthotic intervention) and the amount of stabilizing transverse load exerted by an

orthosis on the spinal curve. Mathematical modeling of the spine-orthosis system involves inelastic buckling analysis of an initially curved and transversely loaded flexible column. The model can stimulate the interaction of different types of orthoses with the spinal curve.

Progress — This analysis examines the stability of an unsupported (without an orthosis) scoliotic spine as a function of: the magnitude of the curvature; and the curve pattern, such as single, double major, or primary and compensatory curves. Furthermore, it evaluates the stability of an orthotically supported scoliotic spine as a function of: the magnitude of the curvature, the end support conditions indicating the extent of motion constraint imposed by an orthosis on the ends of the curve, and the magnitude and type of the stabilizing transverse load exerted by an orthosis on the curve.

Preliminary Results — This study provides a biomechanical explanation as to why larger curves are more progressive than smaller curves, and why a brace is only effective in small and moderate degrees of curvature. Furthermore, this study shows that a double major curve has a greater load-carrying capacity and, therefore, is more stable than a comparable single curve with a compensatory curvature. These results are in general agreement with the clinical findings based upon retrospective studies of patients undergoing orthotic management for scoliosis.

Mechanical Analysis of Cervical Spine Stabilization Techniques

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The objective of this study is to develop a methodology for analysis of spinal motion with controlled loading, apply this methodology to accepted types of posterior cervical spine stabilization, and develop and test an improved stabilization method.

Progress — Previous reports have described a successful method of determining force-displacement behavior of a cervical segment. Using this method, posterior stabilization techniques were tested for a flexion-distraction lesion at C5-6 and compared with each other as well as the intact spine. We found that interspinous wiring was effective in restricting flexion-extension, but may not provide enough stability with torsional and lateral bending forces. A segmental wiring technique simulated the stiffness of the intact spine in all planes but allowed less excursion at higher forces.

Preliminary Results — Over the past year, a posterior stabilization device has been designed, prototyped, and revised. The design objective of the device was to retain the stability advantages of both interspinous wiring and segmental wiring techniques while discarding the complexity of application and lack of versatility of the segmental wiring techniques. The device consists of a set of laminar clips which do not invade the neural canal or facet joints coupled together with rigid struts which may be conformed to many configurations. The device has been successfully tested on preserved cervical spines.

At present, the new device is being tested on fresh cadaver cervical spines using the methods previously described. Comparisons will be made with the intact spine as well as the fixation technology previously tested.

Results of this study are currently being used to assist in selecting the appropriate stabilization technique for disruptions of the cervical spine.

Effects of Low Back Pain Treatment Modalities on Lumbar Facet Loading

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — A majority of those who comprise the working population in the United States will suffer from low back pain and sciatica at some time in their lives. Many times these symptoms are secondary to derangements of the lumbar intervertebral disc. A common accompaniment to disc disease is facet arthropathy. Treatment options for lumbar disc disease include discectomy and chymopapain injection, which alter the load-bearing behavior of the disc. Clinical and experimental evidence indicates that an alteration in the mechanical behavior of the disc produces loss of alignment and abnormal movement and loading of the facet joints. The resulting changes may lead to progressive degeneration of the facets, development of osteoarthritis, and back pain.

The objective of this study is to obtain data describing alterations in load-bearing characteristics of facet joints of lumbar spine segments following simulated treatment modalities for lumbar disc disease. During this study we will test cadaver spine specimens as a function of treatment modalities and physiological load types for various lordotic configurations of the lumbosacral spine. We will also measure facet joint loads using a pressure sensitive film inserted between the articulating facet surfaces at L3-4, L4-5, and L5-S1 segments before and after discectomy or chymopapain injection at L4-5 disc.

Future Plans — With data, we will have a rational basis to design clinical trials for a physician to use in choosing between two effective treatments, especially in the case of patients with pre-existing pathology in facet joints. The data will also help establish guidelines for prescribing post-treatment activities in such patients.

Clinical Biomechanics of the Cervical Spine (Human)

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Sponsor: National Institutes of Health

Purpose — Injuries of the cervical spine represent one of the most physically disabling injuries compatible with survival. They cost the society an estimated three quarters of a billion dollars per year in the United States. Although there have been a multitude of clinical studies, there are only a few studies that have been attempted to analyze the various surgical decompression and stabilization procedures that are used for the cervical spine trauma patient. The purpose of the present proposal is to study a realistic cervical spine injury model regarding changes in its stability due to several surgical decompression and stabilization procedures. Fresh cadaver cervical spine specimens will be utilized to model the

clinically relevant hyperflexion injury. Surgical decompression procedures, e.g., laminectomy and facetectomy, also will be modeled as well as several surgical stabilization procedures. The immediate stability of the spine models as well as their failure strengths will be determined. One of the most significant aspects of the experimental protocol is the determination of a three-dimensional stability of the injury model after every injury and stabilization procedure utilizing the 3-D spinal motion measurement techniques pioneered at the Yale Biomechanics Laboratory. The significance of the proposed study will be in several different areas. The results will provide a direct measurement of the relative loss of stability due to a decompression procedure as well as a relative evaluation of the various surgical stabilization procedures. Additionally, 3-D physical understanding of the entire lower cervical spine will be determined to provide a better understanding of the mechanics of normal, injured, and surgically stabilized cervical spines.

Three-Dimensional Kinematics of the Lumbar Spine (Human)

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Sponsor: National Institutes of Health

Purpose — Based on the significant findings of the preliminary study conducted by the investigators, a 3-year research program is proposed to study three-dimensional kinematics involving range and pattern of motion of segments obtained from 30 fresh cadaver lumbar spine specimens. The objective of the proposed research will be met by conducting *in vitro* experiments using the test facilities and instrumentations specially designed, developed, and tested for this purpose. In addition to the traditional modes (Flexion/Extension, Lateral bending, and Axial rotation), three-dimensional motion of the lumbar spine will be studied in 10 other loading planes (15 degrees apart) that lie in between sagittal and frontal planes. All modes of motion of the lumbar segments will be studied (with and without compressive preload) for the independently and incrementally applied moment loads and shear loads. The kinematic data will be obtained under four conditions: 1) intact motion segment; 2) motion segments with posterior elements transected; 3) motion segments with transected posterior half of the intervertebral disc; and 4) motion segments with transected anterior half of the intervertebral disc. The three-dimensional kinematic characteristics of the lumbar motion segments will be studied in terms of the following kinematic parameters: 1) range of motion in each plane of loading in terms of total rotation and translation about and parallel to the screw axis, and their motion components along the three mutually perpendicular axes of a reference system; and 2) parameters of the screw axis in terms of direction cosines and coordinates of the point of intersection of the screw with a prescribed plane. A total of 30 lumbar spine cadaver specimens will be tested. The data collected from the motion segments of these specimens will be analyzed statistically to test the differences in means of kinematic parameters of the intervertebral motion. The significant contribution of the proposed research will be to provide the signature data or description of the 3-D kinematics of vertebral motion and its normal variation in a quantitative form for each level of the intact and transected motion-segments of the human lumbar spine.

Biomechanical Studies of Idiopathic Scoliosis (Human)

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Sponsor: National Institutes of Health

Purpose — Idiopathic scoliosis is a disease in which the spine develops a progressive curvature. Its cause is unknown and if untreated, it may result in gross deformity. Approximately one person in 500 suffers from this disease.

The overall purpose of this investigation is: 1) to develop a better understanding of the mechanical factors involved in the initiation and progression of idiopathic scoliosis; and 2) to apply this information to improve the methods of treatment and to develop means of prevention.

Because of the difficulty of dealing with the anatomical complexity of the vertebral column, a basic feature of this program is the use of a computer-generated analog of the spine. Studies of model scoliotic spines will be made in conjunction with clinical studies to provide vital information regarding the three-dimensional morphology of the curves, their progression, and their correction. The knowledge gained from these studies will help to base treatment on more rational and objective grounds, and the understanding provided may be essential to the discovery of its etiology.

The Traumatology of the Head and Spine (Monkey, Human)

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Sponsor: National Institutes of Health

Purpose — The project is concerned with the dynamic behavior of the brain and spinal cord under impact loading. The main focus will be the construction of structural finite-element computer models of the human and rhesus head and neck. To support the above goal, we propose to: 1) exercise the first-generation, linear finite-element (FE) computer model of the human head and neck to crown impact with and without padding protection; 2) improve the capability of the present FE model by including nonlinear material and geometric properties in its formulation. By so doing, we should extend the ability of the FE model to simulate contact and noncontact impact situations where large displacement and finite strains are expected in the head and neck; 3) construct a similar dynamic model for the rhesus head and neck; 4) perform dynamic tests on fresh human and rhesus autopsy cervical spines to determine its mechanical and failure characteristics in tension, compression, flexion, extension, lateral bending and torsion (These data are prerequisites to a realistic large displacement FE model.); 5) use the technique of computerized tomography (CT) to determine the geometry and inertial tensor of the rhesus head and neck prior to trauma. The post-trauma CT scans will be used to detect the primary traumatic lesion sites; 6) validation studies, using four rhesus monkeys per year, will be undertaken to verify the effects of the impact vectors on the field quantitites; e.g., linear and angular head accelerations, dynamic intracranial pressure and CT lesions. Four will be used in superior-inferior, occipital and temporal head impacts; and 7) inasmuch as these are very expensive monkeys, we are obliged to do the neuropathology even though they only indirectly support the FE effort. The brains and spinal cords of monkeys will be examined with standard neurohistologic procedures. Particular emphasis will be placed on axon degeneration using silver techniques.

Structural and Mechanical Properties of the Spine (Human)

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Sponsor: National Institutes of Health

Purpose — Our on-going research seeks to identify intradiscal pressure variation both within the intervertebral disc as well as over the end plates. Physiological loading is being carried on unembalmed lower thoracic and lumbar segments at known eccentricities. These data will be used to formulate a finite element model of the disc so that a finite element model of a vertebral segment can be developed.

Characterization of Morphologic Changes in Scoliosis (Human)

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Sponsor: National Institutes of Health

Purpose — The proposed research project will utilize a proven system of *in vivo* three-dimensional radiographic analysis to study both the early- and long-term morphologic changes associated with the idiopathic adolescent spine. Three major categories of scoliosis treatment will be studied—observational, bracing, and fusion. Specifically, this study will be directed towards documenting the effects of growth and treatment on the three-dimensional morphology in the idiopathic adolescent scoliotic spine. The study results will also be evaluated to determine if there exist predicators of not only the progression of the untreated deformity, but also the relative success or failure of standard treatment programs.

Mechanism of Cervical Spine Injuries

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Sponsor: National Institutes of Health

Purpose — The purpose of this project is to produce clinically relevant injuries in cervical spine specimens under controlled high-speed trauma. Load measurements during trauma and plain X-rays, CT scans, and three-dimensional stability measurements are to be carried out before and after trauma to provide an assessment of the loss of stability due to trauma.

Progress — A trauma-producing apparatus has been constructed and is functional. It consists of a drop tower with a vertically oriented tube in which weights of varying magnitude may be dropped from different heights. At the base is a specimen-holding table that can locate the specimen in any orientation and position with respect to the falling weight. A multi-dimensional load cell is provided between the specimen and the positioning table. A separate machine for measuring three-dimensional stability of the specimen, before and after trauma, has been designed and constructed. Presently, studies are being carried out to evaluate the machine.

The deformation of the specimen during trauma will be documented with the help of a high-speed (3,000–6,000 frames per second) 16 mm movie camera. A couple of tests have been conducted using spine specimens and a demonstration model of a high-speed movie camera, in which the results were successful. Finally, 30 canine spine specimens have been prepared for the first series of tests.

C. Human Locomotion and Gait Training

[*See also pgs. 10, 19, 35, 57, 59, 60, 61, 62, 275*]

A Low-Cost Gait Recording System

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Sponsor: Northern Ireland Prosthetics, Orthotics and Aids Service

Purpose — The aim is to produce a low-cost, modular, portable system that will allow clinicians to record some parameters of gait. It will permit clinicians to carry out comparisons of gait measurements over long periods of time, and to provide an analysis of the gait pattern.

The Foot Pressure Profile Platform (FPPP) is a low-profile plate with 512 load cells that depict and analyze discrete areas of pressure beneath the foot. There is an electrogoniometric system for measuring the angular movements of joints, and a step mat which depicts stride length and timing. All are interfaced with a low-cost BBC computer. The system can be used in hospitals without architectural alterations, and is easily set up for use.

The FPPP is now in production, and can be programmed to suit individual clinical needs, and the electrogoniometers and step mat are in the process of being integrated into the system. The modules can be integrated separately with the computer, and software can be provided according to need.

Biomechanical Study of Standing and Walking Using Force Plates

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Sponsor: National Rehabilitation Center for the Disabled

Purpose — The objectives of this project are: 1) to establish fundamental biomechanical relationships between center of gravity (c.g.), point of application (p.a.), and ground reaction forces; 2) to estimate the movement of c.g. during human standing and walking by using above relationships; and 3) to develop clinical methods for evaluation of standing and walking performance.

Progress — Commercial force plates (Kistler, 9281B) were used to measure ground reaction forces. A data processing system used in earlier stages included PDP-12 and NOVA-4, and currently HP Model 216 is used.

Preliminary Results — Results and findings through these studies are as follows. Exact expressions for determination of p.a. were derived. These formulae indicate that conventional simple expressions are only approximations under particular conditions which may be satisfied in the ordinary conditions of standing and walking. Fundamental relationships between mechanical parameters, including c.g., p.a., forces and time derivative of angular momentum, were derived. Using above relationships and curve fitting method, movement of c.g. during standing and walking was estimated. From above relationships and measured data, it was evident that fluctuations of p.a. had reflected feature of the force fluctuations. A new index derived from the force record was used to evaluate characteristics during standing. Force fluctuation levels during quiet standing were only slightly higher than those during sitting. The movement of c.g. during

quiet standing seemed to be influenced by respiratory activity and not directly correlated with muscle effort. Basic patterns of force records during walking can be explained by biomechanical interpretaton of c.g., p.a. and force data. During the curve fitting study, it was found that zero level of horizontal force component of the force plate output shifted slightly according to the location of the load (p.a.) and that this zero shift introduced errors in c.g. curve. Better results were obtained after correction of the shift.

Future Plans — Efforts continue to obtain a more comprehensive understanding of standing and walking, and to develop clinical methods for evaluation of standing and walking performance from force data, as well as simple devices to measure standing and walking activities for clinical use.

Assessment of the Effectiveness of Gait in Cerebral Palsy Children

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Sponsor: Scientific and Research Trust, Central Remedial Clinic

Purpose — It is possible to formulate a reliable and objective assessment procedure of the gait of children with cerebral palsy who are independent walkers. This assessment procedure would: 1) help to categorize children in terms of the severity of their disability; 2) it would be easily administered by any physiotherapist with basic pediatric training; and 3) it would be possible to administer in any physiotherapy department requiring the minimum of time, equipment, and expense.

Progress — A total of 60 were included in the project, 30 children with cerebral palsy and 30 non-physically handicapped children. All were between the ages of 4 and 15 years and were independent walkers. All normal children were excluded from having pre- or post-natal problems or any orthopaedic intervention. The study was divided into 3 parts. These included: 1) measuring temporal and linear components and observing the pattern of gait; 2) assessing functional ability; and 3) assessing endurance.

We hope to correlate the temporal and linear components with specific changes in functional ability.

Preliminary Results — While the study is not yet complete, preliminary results show a highly significant difference for velocity (>0.001) with normal children walking faster. There is a significant difference for cadence ($p<0.001$) with normal children showing higher cadence. There also appears to be a highly significant difference ($p>0.05$) for the degree deviation from the expected line of progression. There was no significant correlation between velocity and cadence in cerebral palsy subjects.

In the category of functional abilities, there is an expected highly significant difference between normal and cerebral palsy subjects with $p > 0.0001$. Normal subjects also show greater endurance and require less recovery time. Results appear to be highly similar between all therapists and each child, except for one therapist and one child. On cross-examination of the results, there appears to be no difference between tests taking places, and the child's cooperation and motivation appear to be influencing factors.

A Telemetric Data Acquisition and Processing System for Biofeedback Training and as a Diagnostic Aid for Human Movement Training

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Sponsor: National Institute of Handicapped Research

Purpose — This work is a continuation of a past effort which began with the specific aim of improving gait training of above-knee amputees. The result of previous work was a self-contained portable force and movement measurement system that provided biofeedback of gait parameters. Two transducers, weight and hip angle, were developed and integrated into the MIT STRIDER system. The STRIDER has been used and evaluated by the physical therapy staff at the Massachusetts General Hospital (MGH), and their reactions were enthusiastic.

During the past 7 months, the STRIDER was again used by therapists at MGH. At their request, several small changes were made to enhance performance. For example, an amplifying speaker was added to allow both the patient and therapist to hear the biofeedback without earphones.

Progress — Currently, the second version of the system is being designed and developed. Measurements from the same transducers are put in to a personal computer via a telemetry data transmission system. The personal computer increases the flexibility of the system in many ways. The therapist can alter threshold values and choose among various forms of biofeedback both visual and audio. Also, data analysis can be accomplished with relative ease. Another benefit is the reduction of the size and weight of devices worn by the patient.

A telemetry system has been chosen as well. Alternatives include infrared, AM and FM radio transmission systems. Design parameters such as performance, reliability, and transmitter size were used in evaluating prototype transmission systems. The final choice was to use an FM transmitter/receiver.

Circuitry to interface the STRIDER transducers with the new system have been developed. Through use of voltage to frequency converters, analog signals from the transducers are coded for FM transmission.

Currently, several formats for visual biofeedback via the personal computer are being studied. The goal is to design CRT-based displays which are effective and versatile.

Evaluation of Methods to Measure Locomotion Performance and Activity

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Sponsor: National Institute of Handicapped Research

Purpose — There are now a number of relatively inexpensive methods of measuring characteristics of gait in individual patients and assessing the amount of activity carried out by them. Some of these methods are designed primarily for clinical use; others offer possibilities for evaluating usefulness of experimental devices and treatment methods not available before.

Among the systems being studied are the Moss Gait Mat, a four-channel physiological ambulatory monitoring device that will record the number of steps and heart beats against time for 24 hours, and a questionnaire developed by H.B.J. Day of the Limb Fitting Service in England. Results from these and other methods will be correlated to determine how each (or combinations of them) can be used efficiently.

The Moss Gait Mat has been installed in the Physical Therapy Area and is used routinely with rehabilitation patients. It also is being used to record data before and after treatment in the experimental arthritis treatment programs.

Progress — The past year has been spent in developing a system for counting the heart beats and steps recorded by the four-channel unit. The system is ready for evaluation of sensitivity by recording data that are obtained as the alignment of an above-knee prosthesis. The four-channel physiological equipment should be very valuable in evaluation of prostheses and orthoses.

Quantitative Gait Analysis (Human)

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Sponsor: National Institutes of Health

Purpose — Quantitative gait analysis using computer-aided videomotion analysis, force plates, and electromyography is of recognized value in assessment of gait disabilities and in quantitative evaluation of treatment. Despite dramatic improvements in techniques, gait analysis still lacks widespread clinical utility because of uncertainties relating to data selection, manipulation, and analysis. Since data acquisition is usually limited to a single test session over several gait cycles, one vital problem concerns selection of a gait cycle for analysis that is representative of the patient's gait and is reliable as a basis for clinical decision-making. Another problem relates to the manipulation of large quantities of data generated by measurements of various kinetic, kinematic and electromyographic parameters over several gait cycles to detect clinically significant patterns of performance. This process is further complicated by the fact that gait patterns vary among patients with the same syndrome and, to a certain extent, among normals.

Interpretation may be simplified by using statistical pattern recognition techniques. In order for this approach to be successful, the enormous quantity of data must be reduced to a parsimonious set of features which describe gait patterns accurately. Furthermore, representation of graphic patterns associated with various gait parameters in terms of a discrete set of variables would make numerical comparison more meaningful.

The first part of this study will investigate repeatability and clinical reliability of selected kinetic, kinematic, and electromyographic parameters obtained from repeated gait analyses on normal subjects and two representative groups of orthopaedic patients. The feasibility of using the variance ratio as a criterion for averaging gait cycles to yield a representative cycle also will be examined. The second part of the study will deal with the application of a principal component analysis for representing gait patterns in a concise manner as an initial step to application of pattern recognition techniques.

The effectiveness of the derived features in representing gait abnormalities will be evaluated using the same normal and orthopaedic patient subjects. The results of the proposed study will enhance the clinical effectiveness of quantitative gait analysis by defining practical computer algorithms for selecting and assessing reliability of raw gait data, and by defining techniques for feature selection that can be used effectively in pattern recognition techniques.

Weight Distribution in the Foot Before and After Surgical and Orthotic Intervention for Hallux Rigidus

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Sponsor: Langer Biomechanics, Inc.

Purpose — Hallux valgus deformity with limited motion and pain in the first metatarsophalangeal joint is associated with abnormal weight distribution through the foot in ambulation. A common treatment modality for this condition is the Keller surgical procedure with a total implant and the use of a functional posted foot orthosis postoperatively.

The goal of this study is to evaluate the efficacy of both the surgical technique and the functional posted foot orthosis in improving the biomechanics of the pathological foot in ambulation. In this study we will measure the parameters characterizing the development of weight distribution patterns in the foot (from heel contact through toe-off) within the environment of the shoe using the electrodynogram (EDG). Our subjects for this study will be patients who have been scheduled for the Keller procedure with a total implant at the Hines VA Hospital. We will complete the study over 12 months both pre and postoperatively as well as with and without the orthosis after surgery.

D. Upper Limb Function

Shoulder Stabilization, the Spinal Accessory Nerve, and the Trapezius Muscle

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Sponsor: No funding was associated with this study

Purpose — The purpose of this study is to show that the trapezius muscle, with its spinal accessory innervation, is a very important factor in shoulder girdle stability. Cervical nerves may supply trapezius motor innervation in varying amounts. Methodology consisted of: 1) anatomic dissections; and 2) a retrospective clinical review of objective and subjective findings in 11 male patients, ages 48 to 72 (average age 62), in whom the spinal accessory nerve was surgically removed during head and neck cancer operations.

Anatomic dissections displayed the dual innervation of the trapezius muscle by the spinal accessory and cervical nerves. The clinical review similarly showed that major but varying motor innervation is from the spinal accessory nerve. All patients had drop and internal rotation of the affected shoulder with scapular winging. Abduction in the eight patients measured ranged from 45 to 100 degrees, the average, 73 degrees and the normal, 180 degrees. Forward flexion measured in seven patients ranged from 60 to 140 degrees, the average, 112 degrees and the normal, 180 degrees. With the loss of the trapezius function, the greater humeral tuberosity is unable to pass under the coracoid ligament and the scapula does not rotate, both limiting abduction. In three shoulders measured, muscle weakness generally occurred. Strength ranged from two to four on a scale of one to five, where five was the strongest.

Collectively, these findings indicated a subluxed, unstable shoulder. Subjec-

tively, all nine patients, who could be questioned, had head, neck, and shoulder pain. However severe at first, most patients learned to accommodate the pain. Only one of 11 patients was able to return to work or hobbies, but only briefly, because of the recurrent disease.

We conclude that the trapezius muscle is very important in stabilizing the shoulder joint as it depends chiefly on the spinal accessory nerve for motor supply. Part of motor innervation, however, may be from the cervical nerves. Variations in this dual motor innervation may account in part for variable loss of motor power with loss of the spinal accessory nerve.

E. Other

Control of Metrical and Timing Precision in Human Movement

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Sponsor: National Institutes of Health

Purpose — This study proposes to investigate central nervous system control strategies used to produce accurate movements. Control of voluntary movement is viewed in this study as a stratified process with several levels of control: 1) movements are initiated by high level construction of open-loop motor commands; 2) are executed from a reference frame stabilized by a postural control system and; 3) are modified by sensory feedback during both command execution ("concurrent feedback") and after movement completion using knowledge of results ("delayed feedback"). Skilled movements and isometric force production are evaluated in terms of these three control mechanisms.

Human adult subjects will track various waveforms presented on a visual display by exerting force on a manipulandum with their elbow musculature. Comparison will be made of motor accuracy under a variety of conditions affecting: 1) the predictability of the stimulus (tracking waveform) amplitude; 2) the availability of visual feedback; 3) the degree of postural stability; and 4) the movement of the elbow joint. In most experiments, subjects will track step waveforms on an oscilloscope screen, while, in one experiment designed to distinguish between strategies subserving timing and metrical movement precision, graphical displays will be more complex. Electromyographic activity will be recorded from appropriate muscles during tracking experiments in order to characterize movement strategies at a level of peripheral neural commands to muscles.

Amputees fitted with myoelectrically-controlled arm prostheses will be used in several phases of this study. In one experiment, these individuals will be used as models of the "deafferented arm" in order to characterize this role of peripheral somesthetic feedback in the control of accurate movements in normal subjects. In addition, a pilot experiment is proposed which directly addresses the problem of user control of multiple degree-of-freedom powered arms. It is hoped that the latter experiment will lead to the development of a large-scale research and training program for amputees at Good Samaritan Hospital and Medical Center.

Human Response and Lower Extremity Injury

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Sponsor: National Institutes of Health

Purpose — The mechanics of human injury is a complex process whereby external forces are transmitted to the human musculo-skeletal system. This system responds in the manner of displacements and rotations and stresses are induced in the tissues, and in some conditions, the tissues are disrupted. When the forces are not constant, prediction of injury and the severity of the forces is difficult. This proposal presents a research program investigating the mechanics of lower extremity injury, specifically injuries to the knee, tibia, and ankle that typically occur in snow skiing. Snow skiing is studied because the lower extremity injury rate is high and the forces transmitted to the foot can be measured. Response of the lower extremity also can be measured and safety devices can reduce the high rate of injuries.

Specialized laboratory and field test equipment have been developed to measure and analyze the forces between the boot and the ski and the rotations occurring at the ankle, knee, and pelvis. Integrated EMG from muscle groups during skiing and especially during falling, when severe loading occurs and the likelihood of injury increases, also have been measured and analyzed. The field measurements identify the injury environment and the laboratory experiments clarify how the lower extremity responds to dynamic loading. The true severity of the typical skiing environment and the contributions of the musculature to influence the likelihood of injury will be clarified. The common misconception that the forces of skiing are small compared to typical tibia fracture strength and knee ligament strength will be corrected. The erroneous concept is widespread, extending to standard organizations, the industry and the public alike. The error has a major impact on the design of safety devices, on the evaluation and acceptance of safety devices, and on the training and instruction given the public. Efforts are directed to develop meaningful standards of safety.

Biomechanics of Human Skin

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Sponsor: National Institutes of Health

Purpose — A series of *in vitro* biaxial stress-strain experiments will be performed on rectangular sheets of unembalmed human skin. The purpose is to quantify the anisotropic, viscoelastic response of the dermis to time-varying strains applied simultaneously in orthogonal axes. The stress relaxation and creep characteristics of skin in a biaxial loading environment also will be studied. A governing biaxial constitutive equation for the dermis will be developed based on a material strain energy formulation. These tasks will be addressed for tissue from various anatomic regions to quantify differences in response associated with physiologic function.

A second primary goal is to identify a material property of the dermis, the energy of tearing. This constant describes the tensile failure characteristics of crack or tear propagation in thin sheets of material undergoing large deformations. The tearing energy constant will be quantified from measurements of applied force, displacement, and geometry of simple test specimen configura-

tions. Both the biaxial stress-strain and failure studies will quantify fundamental material properties and response characteristics of normal tissue which are not available from uniaxial test protocols. These data are necessary for rational planning of elective surgical incisions and finite element analyses of proposed closure techniques. In addition, the intelligent design of dermal prostheses requires a knowledge of the skin's mechanical stress-strain behavior in complex loading environments present *in vivo*.

A Model to Study the Mechanical Behavior of Osteoporotic Bone

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Osteoporosis, characterized by a decreased mineral mass, is the most common metabolic bone disease in the United States and has been estimated to affect at least 6 million elderly American men and women. Although the cause of osteoporosis is unknown, it is multifactorial with contributing factors that include reduced physical activity, decreased dietary calcium, and genetics, hormonal, and other related disease states. Osteoporosis is not a severe problem in itself but problems often arise from its complications. An increased incidence of vertebral compression fractures and as many as 100,000 broken wrists each year may be attributed to osteoporosis. Approximately 190,000 late middle age or older Americans fall and break their hips each year. As many as one-sixth of these patients may die from the ensuing complications, while many of the survivors are incapacitated. The late middle or older age group also represents the patient population most likely to require prosthetic joint replacement which may be compromised by osteoporosis.

Nutritional Secondary Hyperparathyroidism (NSH) is a generalized metabolic bone disease characterized by osteopenia, induced by a diet too low in calcium and/or too high in phosphorus. NSH can be induced in laboratory animals through dietary imbalances resulting in an osteoporotic-like condition of the bone. NSH induction is a potential model for studying the effects of osteoporosis on the mechanical behavior of bone and its interaction with a prosthetic device. This study is investigating the histologic characteristics of the osteoporosis resulting from NSH to determine the effect on the mechanical characteristics of the femur before and after femoral arthroplasty.

Stress Analysis of Internal Fracture Fixation of Long Bones

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The objectives of this study are to develop accurate, non-linear, three-dimensional finite element models of long bones treated with compression plate fixation. These models will incorporate a number of important features which exist *in vivo* and which previous investigators have neglected. With the inclusion of these features in these new models, significant differences in the amount of stress shielding may be predicted in comparison to previous models. This in turn may have important implications on present plate application techniques and on the design of future plates.

These models will allow all primary *in vivo* loading modes to be studied individually. These loading modes will include: bending in the plane of the screws with the plated side in tension (bending closed), bending in the plane of the screws with the plated side in compression (bending open), bending perpendicular to the plane of the screws, axial compression, and torsion. Through the use of non-linear, contact-with-friction elements, these models will include the effects of friction and relative motion between the screw heads and the plate and between the plate and the bone. The relationships between these motions and individual screw tightness will be examined parametrically in order to model different degrees of plate/bone fixity associated with different stages of fracture healing. Both intact and osteotomized bones will be modeled using a transversely isotropic material model for cortical bone. The effects of plate/bone conformity will be studied using two limiting idealizations of possible *in vivo* bone geometries. The concept of plate/bone conformity also will be studied in relation to specified amounts of plate prebending. Both plated and non-plated versions of each of these models will be generated in order to evaluate the extent of stress shielding in each loading mode as a result of plate application. The effect of plate material will be analyzed by altering the input material properties to correspond to the two most common plate materials in current use, *i.e.*, stainless steel and titanium alloy.

Validation experiments using *in vitro* models will be conducted for each of the finite element models. Both titanium alloy and stainless steel compression plates will be applied to tubular specimens having simplified geometries. The first geometry studied will be cylindrical having constant diameter. The two geometries for the plate/bone conformity studies will, in one case, have a larger diameter at each end than in the middle, and in the second case, have a larger diameter in the middle than at each end. Separate specimens will be made from bone and magnesium. Axial screw force will be controlled by monitoring the insertion torque applied to each screw. Pressure-sensitive films will be used to determine pressure distributions and contact areas between the plate and bone. Strain gauge will be mounted to the plate and to the bone to measure surface strains. The *in vitro* models will be loaded in all primary loading modes. The data from these tests will then be compared with the predictions from the finite element models.

Postural Sway in Down's Syndrome

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Sponsor: Liberty Mutual Insurance Company

Purpose — Down's syndrome, a leading cause of mental retardation, occurs in 1 out of 800 live births in the United States. Recent advances in genetics, as well as in education and social interventions, have focused attention on the needs and characteristics of children and adults with Down's syndrome. Much of the emphasis has been placed on the mental retardation and the medical problems of these individuals. Relatively little attention has been paid to their characteristic movement deficits, which usually include some degree of hypotonia, or over-relaxed muscles, and increased joint mobility. The nature and the cause of the hypotonia are unknown, but are presumed to be related in part to the small and poorly developed cerebellum that has been observed in postmortem studies of individuals with Down's syndrome.

Preliminary Results — During 1984, we began working in this area with the goal of augmenting our understanding of motor-control mechanisms in Down's syndrome and contributing to therapeutic programs for both children and adults. Preliminary tests examined the motor skills of 25 children with Down's syndrome between 10 and 15 years of age. Although the children showed overall deficits in their skills, they also showed considerable individual variation in achievement and quality of performance. Since all demonstrated difficulty with activities involving static balance, we then began to study mechanisms, using the force platform to measure postural sway. Fifteen children with Down's syndrome, five normal children, and five children with learning disabilities were tested in the Motion Analysis Laboratory. We have evaluated them in a natural stance and a stance with feet together. They have been evaluated in both stances with their eyes open and their eyes covered in order to ascertain the effect of vision. To date, the children with Down's syndrome have shown greater mean sway in both the anterior-posterior and the medial-lateral directions and greater length and area of sway.

Future Plans — During the next year, we plan to test an additional 55 children with Down's syndrome. These children are between 11 and 14 years of age and were part of a longitudinal study of motor development during their first 3 years of life. They will be compared with an equal number of normal children of the same chronological age. The study will include tests of motor skills including balance. Height and weight measurements and medical examinations will allow us to evaluate the inter-relationship of several other variables.

Bone *In Vivo* and *In Vitro* Stress and Strain Patterns: Influence of Age and Activity

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Our laboratory is currently examining the effects of aging and stress on bone mechanical, morphological, and biochemical properties. During maturation, there is a rapid increase in bone mineral followed by a more gradual increase until the third decade of life. With aging, and particularly following menopause, the opposite or a rapid and often debilitating loss of bone mineral may occur with subsequent bone failure. Bone is capable, however, of adapting to increased or decreased levels of activity or stress, and thus the aim of our research is to understand the mechanism(s) by which immature and mature bone adapts to different stress environments (i.e., bed rest — hypoactivity and exercise — hyperactivity), and from which clinical treatment of debilitating bone diseases and/or fractures in the aged and young population can be improved. Changes in bone geometric, biochemical, biomechanical, and piezoelectric properties are being examined.

Preliminary Results — Geometric, structural, and material properties of normal, growing rats and normal, growing primates have been studied. The results of these studies suggest that scalar relationships exist for biochemical and biomechanical properties of rat and primate cortical bone, and extrapolations of experimental data to humans may be possible. Recently completed studies on the

effects of hyperactivity (voluntary and involuntary exercise) and hypoactivity (hind limb suspended hypokinetic model) have provided insight into the role of gravity and mechanical stress on the control and functional adaptation of bone. The results show that significant changes in bone biochemical and biomechanical properties are present after 2 weeks of activity or inactivity in the maturing rat, and these data suggest that immature bone maintains or changes material integrity in response to an optimum stress range.

Future Plans — More recently, we have measured stress-generated electrical currents in normal vitalized bone using a non-contacting current toroid, the former of which are thought to play an important role in maintenance of bone form and in fracture healing. Future studies will examine these stress-generated current potentials in aging, diseased, and fractured bone and bone subjected to different stress environments (hypoactivity and hyperactivity). Examination of growing rat and primate bone biochemical and biomechanical properties will provide additional insight into modeling (cell activation → osteoblastic formation) and remodeling (cell activation → osteoclastic resorption → osteoblastic formation) processes, respectively. Formulation of a theoretical growth model for modeling and remodeling bone may then be possible. Such a model may allow us to predict the behavior of bone in long-term hypokinetic (disuse, microgravity) and hyperkinetic (exercise) conditions.

Control of Posture

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Sponsor: Liberty Mutual Insurance Company

Purpose — To better understand neuromuscular activity during static balance, we have continued this year to study postural equilibrium in healthy individuals and in patients with neurological disorders. Tests are conducted in our Motion Analysis Laboratory using a force platform to measure postural sway.

Progress — In 1984 we devised a new method for interpreting the data. The fore-aft and the side-to-side displacement of the center-of-foot pressure serve as the *X* and *Y* coordinates for a single plot defined as the stabilogram. The standard methods used to interpret stabilograms include visual inspection and the calculation of mean sway amplitudes, mean sway radius, length of sway path, and frequency of sway. Although the standard analytic methods are useful in quantifying the sway path, they contribute little to understanding the motor-control scheme that directs the movements

Future Plans — A new conceptual tool for modeling postural sway is being developed at our center based on the data from stabilograms. We have modified the standard stabilogram software to formulate a simple mathematical model that can be used to describe the data. Unlike previous methods of analysis, our method relies heavily on analyzing the direction and the length of sway path for each coordinate of the stabilogram. We are presently testing our method and the associated mathematical model by re-evaluating previously recorded stabilogram data. We hope to devise a model that has both physical meaning and clinical utility.

VII. Wound and Fracture Healing

[See also pgs. 4, 46, 194, 215]

Electrical Stimulation for Augmentation of Wound Healing

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — We propose to undertake an analysis to determine whether electrical stimulation can provide exogenous influences that augment wound (ulcer) healing. The analysis will consider the augmentation of wound healing resulting from the interaction of electric and/or magnetic fields with cellular structures and the desposition of heat in the damaged tissues. The field interaction analysis is important because of the possible influence of induced forces on the transport across cell membranes and the movement of charged particles within the damaged tissue. These factors can alter the electric potentials and currents associated with normal connective tissue repair processes. The heat deposition analysis is important because a vigorous inflammatory response appears to aid in controlling microbial contaminants and enhancing the rate of wound healing. This aiding effect is related to the diminished blood flow and concomitant reduction in oxygen delivery to the wound area. The lack of sufficient oxygen negatively affects cell replication, neovascularization, collagen synthesis, and leukocyte function.

Progress — The analysis will be conducted by a medical doctor and electromagnetics engineer working collaboratively to elucidate mechanisms by which electric and/or magnetic fields can augment wound healing. The analysis will include blood and its components, hemorrhagic responses, inflammatory responses, fibroplasia, epithelialization, scar maturation, etc.

Enhancement of Wound Healing Using Synthetic Skin, Electrical Stimulation, and Hyperbaric Oxygen Therapy

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Sponsor: Non-designated from Ethicon/Johnson & Johnson

Purpose — The beneficial effects of electrical stimulation in bone repair have been firmly established. Recent literature also documents increased collagen production and epithelial stimulation in the presence of electrical currents which, in early studies, have also demonstrated accelerated wound healing of decubitus ulcers. The mechanism of this action is believed to occur through increased tensile strength and organization of collagen production and cellular maturation. A variety of human and animal studies have shown the bio-compatibility of bovine dried collagen which is used in synthetic skin, already approved for human studies, and also in dietary consumption with commercial sausage casing. In the laboratory at UMDNJ/Rutgers Medical School, a unique crosslinking technique has been chosen that promotes maximal ingrowth of fibroblasts and angiogenesis as well as allowing collagen production.

Progress — The topical hyperbaric oxygen therapy has been routinely used for decubitus ulcer patients at VA Medical Center, Lyons for the past 2 years. This treatment is relatively simple, safe, and inexpensive. It is easily tolerated by patients. It shortens the patient's suffering, eases the nursing effort, and no adverse reactions have been observed. The combination of hyperbaric oxygen and the use of synthetic skin may or may not further accelerate the healing process of the decubitus ulcers, but is an area which needs to be studied.

Optimal wound healing in the proposed clinical circumstances may occur with utilization of both electrical stimulation and collagen sponge dressings. The goal of our studies would be to establish an initial pilot study over a year's duration of approximately 24 patients with use of the electrical stimulation, synthetic skin, and hyperbaric oxygen therapy.

We believe the techniques used, which have previously been approved for human studies and are commercially available, are of minimal risk either in terms of immunogenic or infectious complications. Electrical stimulation has been used in bone healing as well as pain control and similar levels proposed for the study. We anticipate no adverse effects. Careful clinical monitoring along with daily and weekly summaries would terminate any adverse chronically observed effects if they were to develop.

Electrical Stimulation of Mandibular Fractures (Rabbits)

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Sponsor: National Institutes of Health

Purpose — Electrical stimulation of bone growth has been demonstrated in animals, and has been reported to be a clinically useful modality for testing nonunions of long bones. We propose to evaluate the use of electrical osteogenesis in accelerating the healing of mandibular osteotomies. Sixty rabbits will receive a standardized unilateral mandibular osteotomy. In 30 rabbits, 10 microamperes DC will be administered to the fracture site from an implanted power unit using platinum wire electrodes. The remaining animals will be implanted with a dummy power unit. The rabbits will be sacrificed at 2 to 6 weeks post-fracture, and the degree of healing in the stimulated and sham-stimulated animals will be compared histologically using a numerical grading system with blind scoring. If successful, the proposed work would lead to a clinical study and, ultimately, to the possible use of electricity to reduce morbidity in patients with mandibular fractures by decreasing the healing time.

Acceleration of Fracture Healing Electrical Fields (Rabbits, Rats)

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Sponsor: National Institutes of Health

Purpose — The object is to continue research investigating the effects of applied electrical fields on the acceleration of fracture healing in laboratory animals. The proposed research is designed to determine the optimum parameters of applied (exogenous) electricity for accelerating fracture healing, to determine the role of stress generated (endogenous) electricity in fracture healing, and to determine the mechanism of electrically induced osteogenesis at the cell level.

Progress — Methods to be used include the comparison of the osteogenic response of *in vitro* fetal rat tibia and *in vivo* healing rabbit fibula to constant direct current, various pulsed unidirectional electric fields, and various electromagnetic fields. Osteogenesis and bone healing will be evaluated by incorporation of tritiated thymidine, Ca45, and 35S04 as well as maximum resistance to bending as determined by an Instron Testing Machine. Stress generated potentials will be measured in fracture calluses. Origin of stress generated potentials will be evaluated by altering collagen in tendon biochemically. The mechanism of action of electrically induced osteogenesis will be sought by determining pO2 and pH changes in the vicinity of a cathode, changes in surface of cell membrane, mitochondria release of calcium, cellular proliferation and migration, and collagen and proteoglycan biosynthesis and processing.

Electrical Stimulation of Osteogenesis Using Selected Techniques

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — This initial report is for a research project involving the use of various, selected electrical stimulation techniques for bone growth and repair. The overall goal is to determine an effective stimulation technique to be employed in research that will evaluate the appropriateness of electrical stimulation therapy to remobilize patients with loose prosthetic devices (trauma and irritation present) and patients with osteopenia (trauma and irritation absent). The specific aims are to: 1) define the dose response relationship in magnetic field amplitude for electromagnetic stimulation (EMS) produced by a sinusoidal waveform; 2) determine whether trauma and irritation are required with EMS produced by either a sinusoidal or a square-pulse burst waveform; and 3) compare the efficacy of direct current stimulation (DCS), EMS by a sinusoidal waveform, and EMS by a square-pulse burst waveform in the same animal model.

Throughout this project, the tissue site selected for electrical treatment will be the rabbit tibia medullary canal.

Progress — Three sets of studies will be performed.

1) *Dose Response Relationship in Magnetic Field Amplitude for EMS by Sinusoidal Waveform.* Three groups of 12 animals each will be employed. Group 1: One week of acclimation, bilateral intramedullary rod insertion, and implantation surgery, 4 weeks of healing, 3 weeks of unilateral treatment, sinusoidal EMS A versus no EMS, terminate; Group 2: As in Group 1 but with sinusoidal EMS B versus no EMS; Group 3: As in Group 1 but with sinusoidal EMS C versus no EMS. Sinusoidal EMS A (B or C) is a type of EMS produced by a specific sinusoidal waveform.

2) *Necessity of Trauma and Irritation with EMS by Sinusoidal Waveform or Square-Pulse Burst Waveform.* Two groups of 12 animals each will be employed. Group 4: One week of acclimation, unilateral intramedullary rod insertion, and implantation surgery, 4 weeks of healing, 3 weeks of bilateral treatment with sinusoidal EMS O, terminate; Group 5: As in Group 4 but with square-pulse burst EMS. Sinusoidal EMS O is optimal of sinusoidal EMS A, B, or C. Square-pulse burst EMS is a type of EMS produced by a specific square-pulse burst waveform.

3) *Efficacy of Three Different Electrical Stimulation Techniques in the Same Animal Model.* Three groups of 12 animals each will be employed. Group 6: One week of acclimation, bilateral intramedullary rod insertion, and implantation surgery, 4 weeks of healing, 3 weeks of bilateral treatment, DCS versus sinusoidal EMS O, terminate; Group 7: As in Group 6 but with DCS versus square-pulse burst EMS; Group 8: As in Group 6 but with sinusoidal EMS O versus square-pulse burst EMS.

For each individual study, the biological response will be evaluated by histomorphometry of new bone formation, necrotic tissue, and selected cell types within medullary canal tissue.

Electrical Osteogenesis—Mechanisms and Causes of Failure

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The goal of this study is to investigate the mechanisms underlying the electrical stimulation of fracture healing by continuous direct currents. This is accomplished by carrying out several biophysical, biochemical, and biological measurements in a canine experimental model of fracture with and without electrical stimulation.

Progress — The experimental model is an osteotomized canine radius with implanted Ag/Ag Cl electrodes. Electrical field measurements and roentgenograms are obtained weekly. The dogs are sacrificed at 3, 6, and 9 weeks postosteotomy. In selected dogs, revascularization of the fracture is determined by microangiography performed using India ink just before sacrifice. After sacrifice, mechanical rigidity of the radius is measured using a 4-point bending apparatus. Osteogenesis may then be quantitated by histomorphometric and biochemical measurements.

Electrical measurements in a fresh fracture model and a minimum injury model have been used to determine the electrical field pattern in bone imposed by the exogenous direct current signal. Quantitative evaluation of a delayed healing model in canine radius using biomechanical, histomorphometric, and biochemical measurements has been completed. Mechanical rigidity has been found to correlate well with revascularization and callus remodeling in the fresh fracture model. An experiment to determine the optimum values of electric field in the fracture as well as the source current for direct current stimulation of osteogenesis in this model is in progress.

Studies on Factors Affecting Orthopaedic Infections (Human, Hamsters)

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Sponsor: National Institutes of Health

Purpose — This research addresses diagnostic and treatment problems associated with infection in three separate types of orthopaedic patients.

The first type have injuries in which the wound is open and probably contaminated by bacteria. The problem of infections in orthopaedic surgery is of special interest because of the use of foreign bodies in the management of fracture.

One decision involves whether or not to close a wound with sutures. The second decision is whether or not to use internal fixation devices in the presence of a possibly contaminated field. Laboratory procedures that would quickly inform the surgeon of the level of bacterial contamination would aid in these decisions. Scientific evidence of the role of internal fixation in high rates of infection would also help. Quantitative wound culture studies are proposed to answer the question of whether or not there are increased rates of infection with the use of internal fixation.

The second type are individuals who develop infections many months after an implant or total joint insertion. The question addressed in this situation is whether or not the existence of a sensitivity to one or more of the components of the implant might contribute to the likelihood of an infection.

The third type are patients in whom the diagnosis of the etiologic agent is difficult because the appropriate sample for bacteriologic culture is not easy to obtain or because there are antibacterial substances in the specimen. The use of rapid immunologic techniques is proposed to aid in the rapid diagnosis of septic arthritis and osteomyelitis. The studies proposed in this application should aid the orthopaedic surgeon in patient management decisions.

Clinical Study: Effectiveness of EBI Bone Healing System™ in Treating Femoral Head Necrosis

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — This study seeks to determine the degree of effectiveness of the EBI Bone Healing System™ in the treatment of avascular necrosis (AVN) of the femoral head over a 12-month period.

Progress — The study will be a multicenter (15 to 20) trial. Each center will be asked to submit 25 patients. Patient selection criteria determine that those included in the study are likely to suffer femoral head collapse and subsequent total hip replacement. Each patient will be supplied with the EBI Bone Healing unit. This study will require that patients wear this device for 8 to 10 hours per day (ideally during sleep), 7 days per week for a period of not less than 6 months. Patients with unilateral AVN involvement may be partially weightbearing (3-point gait) with two crutches for the first 3 months. After the first 3 months, patients may bear weight as tolerated. For the first 3 months, patients with bilateral involvement will be instructed to use two crutches with a 4-point gait. After the first 3 months, the patients may bear weight as tolerated. Each patient will be asked to return for follow-up assessment at 3 months, 6 months, and 12 months after starting treatment. AP and lateral X-rays and required forms will be submitted to EBI for each follow-up.

To assess the effectiveness of the EBI pulsed magnetic field in the treatment of avascular necrosis (AVN), patients will be evaluated functionally as well as radiographically: 1) *functional analysis*. Using Charnley modified D'Aubiqne and Postel numerical classification grading system, a 6-point scale for each of these categories (pain, function, and mobility) will be used. For each category a "1" will represent the most severe condition and a "6" will represent the least

severe condition; 2) *radiographic analysis*. Both anterior/posterior and frog lateral X-rays will be used to detect changes in the affected hip. In particular, joint space, collapse, avascular segment containment, and cystic lesions will be noted. Additionally, based on the X-ray evaluation, a classification of the lesion will be made using the Ficat classification.

Assessment of Nutritive Skin Blood Flow

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Sponsor: VA Rehabilitation Research and Development Service

Progress — *Fluorescein Studies*. The evaluation of skin blood flow using low dose intravenous fluorescein in patients with peripheral vascular disease is progressing smoothly. Two manuscripts describing recently completed studies are in preparation. The first one describes a retrospective study of fluorescein delivery to dysvascular limbs. In this study the relative delivery of fluorescein to the limb compared to a reference area was measured. The data were then used retrospectively to develop indices of fluorescein delivery to predict skin viability following amputation. A second manuscript examines prospectively the ability of low dose fluorescein delivery to predict skin viability using the indices developed in the previous study. This prospective evaluation has been found to be accurate and promises to be a reliable clinical test.

Helium Studies. The quantitative evaluation of skin blood flow using a helium flux technique is underway. Over the past 9 months, a helium mass spectrometer has been acquired, set up, and has been operational for the past 3 months. Currently, studies are underway examining helium flux/blood flow in normal volunteers. The effects of skin probe temperature, day to day and subject to subject variation are being determined and this study is virtually complete. Within the next quarter we will compare the helium flux method to radioactive Xenon washout in normal volunteers and compare these data with washout rates of intravenously administered low doses of fluorescein. This study will allow direct comparison of three independent measures of blood flow in the same subject.

Altered Collagen and Wound Metabolism in Non-Healing Diabetic Ulcers

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — This project is designed to test the hypothesis that potentially correctable metabolic abnormalities may interact with ischemia, neuropathy, and infection to obstruct healing of diabetic ulcers. Subjects include diabetic and nondiabetic patients admitted to the Seattle VA Medical Center Amputation Service who may require lower extremity amputation as a result of diabetes and/or vascular disease. We will test whether recent poor glycemic control, abnormal ascorbic acid metabolism, altered zinc availability to injured tissue, and increased nonenzymatic glycosylation of dermal collagen are associated with and potentially responsible for failure of wound healing that leads to amputation in diabetic individuals.

During the initial project year we have developed biochemical and vascular methods and established protocols for studying potential amputation patients

when they become available. Glycemic control in diabetic patients will be documented by measurements of fasting plasma glucose and glycosylated hemoglobin. Ascorbic acid levels will be determined in samples of plasma from all patients and in leukocytes and dermal tissue from selected patients, measured by high performance liquid chromatography. Zinc levels will be measured in samples of plasma leukocyte and wound tissue by atomic absorption spectrophotometry. Methods have been finalized for extraction of collagen from skin and wound tissue specimens from amputated limbs for subsequent measurement of the extent of glycosylation of collagen fractions. Nutritional status is being evaluated by a panel of laboratory nutritional indicators measured in fasting plasma. Vascular status of diabetic and nondiabetic amputation subjects is being documented by standardized measurements of limb transcutaneous oxygen tension (T_CPO_2) and segmental Doppler blood pressures.

Preliminary Results — During the first 10 months of this study we have studied 40 diabetic individuals who have been candidates for or actually received limb amputations. Twenty-eight nondiabetic amputees with peripheral vascular disease have been enrolled. In addition many of the biochemical and vascular measurements have been standardized in 10 healthy nonsmoking elderly males without diabetes or vascular impairment. Vascular and plasma metabolic measurements have been made in 60 diabetic individuals admitted to the same hospital but who have not had amputations or lower extremity ulcers. Preliminary data analysis confirms that zinc and ascorbic acid metabolism may be abnormal in diabetic and nondiabetic patients who require lower extremity amputation.

Future Plans — During the second year of the project we will continue to enroll subjects in these patient categories. A subgroup of patients will be given experimental iatrogenic microwounds inflicted on the limbs 7 days prior to amputation in order to derive a semiquantitative independent index of cutaneous wound healing to correlate versus the metabolic parameters. We hope to be able to identify metabolic abnormalities that may contribute to limb loss and wound failure in diabetic individuals.

Scientific Basis for a New Protocol in External Fixation of Fractures

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — This project is intended to advance the state of the art in the external fixation method of fracture management. The proposed strategy will use objective criteria to determine the earliest safe time to begin partial weightbearing and apply electrical stimulation as a preventive measure against delayed union.

Progress — We have developed a method of *in vivo* mechanical testing of fractures in a canine tibia model. This method obtains a stiffness parameter that characterizes the healing fracture by determining the rigidity of the bone-fixator composite as a function of post-fracture time. The influence of electrical stimulation at different, physiologically significant, stages of fracture healing on

this healing curve is investigated experimentally. The stimulation will be applied in two separate phases—middle and late phases of fracture healing. Stimulation of fractures in the early phase (i.e., fresh fractures) will not be attempted since there is no evidence to date of acceleration of healing of fresh fractures by electrical stimulation. Histomorphometric methods will be used to measure new bone formation. Methods for evaluation of the status of healing also will include roentgenography and microangiography and *in vitro* tensile testing of the tibia at sacrifice.

Noninvasive Quantification of Fracture Healing

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The goal is to develop a noninvasive method to quantify fracture healing. Such a tool would be useful both clinically, in early diagnosis of delayed unions and clinical healing, and in research to diagnose various rehabilitation protocols.

Progress — Two and one-half years of clinical testing on 28 patients with closed tibia fractures has shown a statistically significant difference between the natural frequencies of the fractured tibia and the contralateral normal tibia. The natural frequencies of the fractured tibia have been shown to increase over time for normal healing, approaching the values of the contralateral normal tibia. Fractured tibia classified as nonunions have been shown to have different natural frequency healing curves compared to normal healing tibia.

The dog has been chosen as a model to find the correlation between the natural frequency of the healing bone and the breaking strength of that bone. This is being accomplished by producing oblique osteotomies in the radii of 21 dogs. Natural frequency testing is being performed weekly on each of the dogs. Two dogs are also being sacrificed weekly and both radii removed. The radii are submitted to Computerized Axial Tomography to find the cross-sectional area of the cortex. The radii are then subjected to torsional loads until the breaking strength is determined.

Morphological and Clinical Studies of Microwounds in Ischemic Human Tissue

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The goal of this project is to study in a systematic fashion morphological and clinical features of small standardized wounds created on the lower extremities of patients with severe peripheral vascular disease (PVD) necessitating amputation.

Progress — The wounds are created with a Simplate II bleeding time device under sterile conditions at locations immediately distal to the planned site of amputation and at a variety of clinically and biologically relevant time periods for the study of wound healing. Wounds are examined clinically immediately prior to amputation and then excised from the amputation specimen fixed for morpholog-

ical studies. When normal control subjects are used, standard skin punch biopsies are used to remove the microwounds.

Standard techniques for tissue fixation, sectioning, and evaluation of all samples by light microscopy and of selected samples by transmission and scanning electron microscopy are used. Morphological events of healing are then compared with forearm wounds of young adults from previous studies and leg microwounds from age-matched controls. Transcutaneous oxygen tension ($TcPO^2$) at the site of microwounds, the clinical appearance of the microwounds, the outcome of the amputation, and a variety of risk factors for PVD, such as smoking, diabetes, and hypertension, are also correlated with microwound healing.

Preliminary Results — During the past year, seven additional patients have had microwounds created prior to amputation and ten normal elderly subjects have had microwounds created and biopsied to serve as age-matched controls for the amputation patients. In addition to the morphological studies of the normal and abnormal wound tissue, immunohistochemical studies also have been performed on all normal and selected abnormal wounds. The normal subjects have wound repair that is clearly more advanced than patients undergoing amputation, but it is significantly more delayed than the normal young adult forearm microwounds. The observations of normal elderly leg wound healing are unique and will provide an important point of reference for both past and future investigators regarding wound healing in diabetic and ischemic patients.

VIII. Properties of Muscle

A. General

[*See also pgs. 181, 185*]

Automatic Decomposition of the Clinical Electromyogram

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The electromyographic (EMG) examination plays an important role in the diagnostic evaluation of many neuromuscular disorders. It involves recording an electrical signal from a contracting muscle by using a needle electrode and assessing the motor-unit action potentials (MUAPs) of which the signal is constituted. This assessment is still widely performed in a qualitative fashion by watching the EMG signal as it flashes across an oscilloscope screen and by listening to its sound.

There is a widely felt need for ways to quantitate EMG analysis in order to make it more objective, more reproducible, and more diagnostically sensitive.

Progress — A number of methods have been proposed for quantitating EMG analysis. The ones which extract MUAPs from the EMG signal have proven to be the most diagnostically sensitive. To date, however, the difficulty of decomposing signals containing more than four or five MUAPs has hampered quantitative analysis of EMGs recorded during any but the weakest contractions.

We hypothesized that advanced signal-processing and pattern-recognition techniques could be used to efficiently and accurately decompose moderately complex EMG signals into their component MUAPs.

We have developed a software package called ADEMG for Automatic Decomposition Electromyography for extracting MUAPs from EMG signals recorded during conventional EMG examinations. The program can extract as many as 16 simultaneously active MUAPs from EMGs recorded at strengths up to 30 percent maximum voluntary contraction. It is designed to analyze EMGs recorded during 10-second constant isometric contractions using a standard concentric needle electrode and thus conveniently supplement the conventional qualitative EMG examination. The analysis time is 90 seconds on a PDP-11/34 computer.

Preliminary Results — We are in the process of collecting a database of MUAP properties from healthy subjects and patients with known neuromuscular disorders. Preliminary normative data have been collected for the biceps muscle from 10 normal subjects. Two papers are in press—a technical description of ADEMG and a presentation of the preliminary results. In order to make the ADEMG software more widely available, it is currently being translated to run on an electromyograph manufactured by Nicolet Biomedical Instruments of Madison, Wisconsin.

A Smart Trigger for Real-time Neuroelectric Spike Classification

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Neuroelectric signals recorded from muscle and brain often contain action potentials or "spikes" arising from more than one cell. In order to study the behavior of the individual cells, it is necessary to sort out the spikes. In some applications it is necessary to perform this sorting in real time.

An automatic real-time spike classifier would benefit physiologists engaged in extracellular recordings in muscle and brain. It would also find application in "single-fiber electromyography," a technique for diagnosing neuromuscular disorders. This technique is currently hampered by the poor performance of available spike classifiers. Another possible application would be the decoding of myoelectric signals to control prostheses or functional electrical stimulation.

Progress — Simple electronic devices called triggers have been available for real-time spike sorting for some time, but they tend to be unwieldy to use and to give poor discrimination performance. Computer programs employing sophisticated signal-processing and pattern-recognition algorithms are also available for spike sorting. They are capable of automatic operation and excellent discrimination, but they are too slow to operate in real time. Algorithms used in spike-sorting computer programs can be transferred into an inexpensive, microprocessor-based device which will be fast enough to operate in real time.

Preliminary Results — We are building a device that we call the "Smart Trigger" which will be able to classify as many as eight simultaneously active spike trains. It will identify spike signatures automatically, adaptively track slow changes in spike shape, and make use of fast detection and template-matching algorithms that grew out of our previous work on analyzing clinical electromyograms. The Smart Trigger will employ three M68000 microprocessors in addition to specially designed digital filtering and peak-detection hardware. Funding for this project began in April, 1985.

Ethanol-Induced Cytoskeletal Dysgenesis in Muscle

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The purpose of this project is to develop an animal model in which ethanol-induced myofibrillar dysgenesis occurs and to characterize the ultrastructural abnormality with associated hypotonicity and weakness.

The project plan entails examining *in utero* morphologically damaged muscle when exposed to ethanol. First, female rats will be acclimated to a diet in which ethanol constitutes 36% of their caloric intake. This diet is administered throughout gestation. Muscles from rat pups born of these females will be examined histochemically and ultrastructurally to document alteration in the contractile proteins (myofibrillar dysgenesis). Appropriate control animals will be studied. Blood ethanol and acetaldehyde levels will be drawn periodically on mothers and newborn pups in an attempt to correlate those levels with the degree of damage and manifestation of hypotonicity. Additionally, growth parameters of myocytes will be studied employing *in vitro* cultures of cardiac and skeletal

muscle from newborn pups gleaned from the above experimental and control groups. Morphometric data analysis will be generated from both *in vivo* and *in vitro* materials to record the dysmorphogenesis associated with *in utero* ethanol exposure.

Muscle biopsies from the rat pups will be studied using frozen section histochemistry and ultrastructural preparations standard in our pathology morphology laboratory. Ultrastructural examination of cell cultures will be performed using a monolayer recovery technique. Morphometric analysis will be performed on a Zeiss MOP III quanitmat. Blood ethanol and acetaldehyde levels will be performed on a H-P gas chromatograph in consultation with Dr. Dean Tuma.

Evaluation of Spasticity

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Sponsor: Osaka Rosai Hospital

Purpose — Our goal is to develop a system of quantitative evaluation of spasticity where hemiplegic and paraplegic patients are involved. This system keeps records of EMG, covering a full day or more for evaluating spasticity, by using a system of handheld computers which enables us to record all kinds of biological phenomenon during daily activities. We can eliminate many difficulties by measuring spasticity quantitatively.

Measurement and Reduction of Spasticity

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Sponsor: The Multiple Sclerosis Society (UK)

Purpose — The pendulum test was used to assess spasticity in the knee extensors in a group of SCI patients and to evaluate the beneficial effects of dermatome stimulation.

A microcomputer-based instrument was developed to automate the pendulum test data acquisition, analysis, display, and storage of patient data. This system is presently being evaluated as a clinical tool.

The present aim is to optimize the stimulus parameters and to investigate the effects of articular stimulation by knee joint effusion.

Muscle Structure and the Contractile Mechanism (Rabbits, Protozoa)

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Sponsor: National Institutes of Health

Purpose — The objective is to determine the precise molecular architecture of a diverse class of Alpha-fibrous proteins whose role is both structural and dynamic. The chief methods are coordinated X-ray crystallography, electron microscopy, and image analysis. Muscle proteins are a central focus and provide the background for studying related systems. A major aim is to determine the structure and motions in two calcium-dependent protein switches that control contraction. Thus, crystals of the regulatory complex tropomyosin/troponin are

being analyzed, and the topology of the myosin molecule with its associated light chains will be determined to establish models for regulation. The molecular basis of blood clotting is being studied by a similar approach. The structure of fibrinogen will be determined by X-ray crystallography and its packing established in the fibrin clot. These structural methods also will be applied to certain cytoskeletal and cell surface proteins (including those on human parasites) that play important roles in cell form, movement, and interactions. The broad study of these systems is directed towards identifying distinctive features of structure that are essential to their function.

Progress — Knowledge of the molecular mechanisms of contraction and its regulation in normal muscle is needed to account for failure in various heart and muscle diseases. Similarly, a full understanding of blood clotting, and its malfunction in certain cardiovascular diseases, requires detailed information about the structure and interactions of the fibrinogen molecule. We recognize now the vital role of the cytoskeleton and various arrays of internal and external cell surface proteins in normal cell function and in development, and the responsiveness of these structures to cell transformation. The occurrence of fibrous proteins that may be related to muscle proteins at the surface of pathogenic organisms has important medical implications. Our broad study of the structure and interactions of these fibrous proteins will lead to a deeper understanding of both normal and abnormal cellular function.

Quantification of Dynamic Muscle Strength (Human)

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Sponsor: National Institutes of Health

Purpose — Manual materials handling (MMH) activities can cause high stresses on the musculoskeletal system. The dynamic nature of these tasks, such as lifting, preclude the use of the traditional concepts of human strength: isometric and isotonic contractions. Instead, the novel development of isokinetic muscle contraction has expanded the study of dynamic muscle strength. Isokinetic contractions occur against a lever arm which controls the velocity of movement and offers resistance proportional to the muscle dynamic tension developing capacity at every point in the range of motion. Thus, the maximum demand can be placed on the muscle at any time, and, by selecting appropriate velocities, muscle power can be maximized. The proposal is to quantify the dynamic strength of those muscle groups that relate to MMH activities in a four-phase research plan: 1) investigate in detail the dynamic properties of muscle strength for those muscle groups used most often in manual materials handling activities; 2) compare the measurement of these properties on the stationary Cybex isokinetic dynamometer with those measured on the portable Mini-Gym isokinetic dynamometer through correlation analysis; 3) devise dynamic strength tests that would be representative of the actions and muscle groups for manual materials handling activities and that could be easily implemented for pre-employment strength testing; and 4) compare the dynamic strength tests with existing static and psychophysical tests and with predictions from dynamic models.

Alterations in Skeletal Muscle with Use and Disuse (Rats)

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Sponsor: National Institutes of Health

Purpose — Our primary objective is to continue experiments designed to elucidate the effects of use (exercise-training) and disuse on fast and slow skeletal muscle, and to determine to what extent and by what mechanism exercise-training protects against the development of fatigue. Our long-term objective is to understand the molecular mechanisms controlling muscle function such that this knowledge can be utilized in the prevention of fatigue and disease, and in rehabilitative medicine.

The effect of exercise-training and long-term disuse on muscle function, and the etiology of muscle fatigue, will be studied in the rat. The physiological studies will include an *in situ* and *in vitro* evaluation of the contractile properties of the slow-twitch soleus, and fast-twitch extensor digitorum longus (EDL) at rest and during acute contractile activity. The intracellular H+ ion concentration will be directly measured using pH-sensitive glass microelectrodes, and pH changes during work determined. The pH changes will be correlated to alterations in substrate levels and contractile properties to assess the role of the H+ in muscle fatigue. The skinned fiber preparation will be utilized to determine how exercise-training, fatigue, and disuse affect sarcoplasmic reticulum (SR) and myofibrillar function. The contribution of myofibrillar and SR ATPase to the total activity will be determined and these activities correlated to maximal shortening velocity and force transients, respectively.

The sarcoplasmic reticulum (SR) will be studied to determine how exercise-training, muscle fatigue, and disuse affect the kinetic properties, phosphorylation, and gel electrophoretic patterns of this membrane system. These experiments are designed to test our hypothesis that the SR controls the intensity and duration of the active state, while the maximal speed of unloaded shortening is dependent on the myosin ATPase activity.

Elasticity, Force, and Fiber Length Changes in Aging Muscle (Rats)

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Sponsor: National Institutes of Health

Purpose — A multidisciplinary program is aimed at elucidating the cellular mechanisms involved in the accumulation and remodeling of muscle connective tissue and the reduced range of movement that occur in aging and/or inactive individuals. The amount and properties of the connective tissue in the muscle belly are influenced by the type of activity that the muscle is subjected to. Connective tissue remodeling is linked with adjustments in sarcomere number so that there is a reduced range of movement as well as an increase in stiffness.

The questions asked include: can regular exercise delay the onset of muscle stiffness by altering the distribution and nature of the connective tissue, and which type of stretch (active, passive, dynamic) is the main factor in preventing muscle connective tissue accumulation and sarcomere loss?

The form and amount of muscle connective tissue will be studied by quantitative transmission, EM, and light microscopic techniques. Changes in endomysial and perimysial connective tissue will be evaluated and the rates of

synthesis of collagen and contractile proteins will be measured to shed light on the remodeling process. Changes in the functional length of muscle fibers will be determined by measuring sarcomere number and sarcomere length. The cellular mechanisms involved in the addition and removal of sarcomeres will be studied concurrently with those involved in connective tissue remodeling. These will be related to the physical and physiologic characteristics of the muscles studied and will include measurements of muscle force, rate of force development, compliance, and elasticity. Both the morphologic and physiologic changes will then be related to the functioning (force production, compliance, and elasticity) of the aging musculoskeletal system.

The data will be of considerable value to those involved in physical therapy, the management of elderly respiratory, orthopaedic and neurologic patients, as well as elderly patients in general.

B. Muscle Contraction

Motor Unit Firing Rates and Recruitment

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Sponsor: Liberty Mutual Insurance Company

Purpose — Muscle contractions are modulated by the number of motor units recruited and their respective firing rates. Our research has documented an interplay between recruitment and firing rates of motor units. The recruitment of a new motor unit appears to have a disfacilitatory influence on the firing rates of previously activated motor units. Theoretically, this influence may operate, at least partially, through the stretch-reflex loop, and possibly by the recurrent inhibition of a specialized neural feedback pathway known as the Renshaw circuit. (The stretch-reflex loop and the Renshaw circuit consist of neural pathways that exert a regulatory influence on the excitation received by the motor unit.) Such a mechanism would be functionally useful since it would provide for the smooth control of muscle output through peripheral neural circuitry, thus lessening the amount of detailed supervision over the alpha-motoneuron pool required from the central nervous system.

Progress — During the past year, we have observed this phenomenon in four muscles of the upper limb (first dorsal interosseous, flexor pollicis longus, extensor pollicis longus, and deltoid), as well as a muscle in the lower limb (tibialis anterior). We studied the occurrence of the phenomenon extensively in 32 motor units of the first dorsal interosseous and in 39 motor units of the tibialis anterior.

A paper describing this work has been accepted for publication by *Brain Research*. Details on the findings of this project were presented at three conferences.

The Myoelectric Signal Decomposition Technique

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Sponsor: Liberty Mutual Insurance Company

Purpose — During the past several years, we have been developing and refining a system for studying the behavior of motor units. The system analyzes in detail the myoelectric signal that can be detected by a needle electrode in a contracting muscle. With this system, we can extract information from the muscle which helps us to understand the nature of the control schemes that the nervous system uses to govern muscle contractions. Our system works in three phases: 1) the data signal acquisition phase; 2) the data preprocessing and decomposition phase; and 3) the analysis phase.

Progress — During 1984, we documented and streamlined the various computer programs that constitute the data signal acquisition phase. These programs were also organized into a unit so they would be readily accessible to the new investigators in our NeuroMuscular Research Center.

We also expanded our collection of computer programs for the analysis phase by adding programs for analyzing the amount of synchronization in motor unit contractions. Synchronization is the tendency for two or more motor units to contract in a fixed time relationship with respect to each other. Our approach to quantifying synchronization begins with comparing the number of occurrences per unit time of time-locked contractions with the number of randomly occurring contractions of two motor units. The synchronization values thus obtained are plotted in several formats, each specially designed to reveal different features of the synchronization behavior.

Improvements in the decomposition technique are detailed in a paper published this year in *EEG and Clinical Neurophysiology.* They were also discussed at two international symposia.

Synchronization of Motor Unit Discharges

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Sponsor: Liberty Mutual Insurance Company

Purpose — Several other researchers have investigated synchronous behavior within a motor-unit group. Due to limitations in detection and analysis techniques, synchronization has never been studied in detail and remains controversial. Our decomposition technique has removed many of these limitations. Incorporating a statistical analysis technique called the conditional intensity, we now can objectively observe and also accurately measure synchronization.

Preliminary Results — During 1984, we devised an algorithm for producing a numerical measure called the synchronization ratio. A synchronized ratio of 1.0 would be expected if two motor units were contracting independently. Preliminary results have shown that: 1) the ratio is greater than 1.0 in all of seven muscles examined; 2) it is more apparent in smaller muscles than in larger muscles; 3) it tends to increase upon recruitment of a new motor unit; 4) it tends to increase when there is a significant sharp deflection in the force output of a muscle; and 5) it tends to increase as a muscle fatigues.

Future Plans — Our studies lead us to believe that synchronization is associated with the involvement of the stretch reflex that may or may not be activated when a muscle fiber contracts. In future investigations, we plan to study the conditions which tend to increase the incidence of synchronization. We also plan to study the phenomenon in normal subjects and in patients with well-specified neural lesions. Through this study, we hope to devise a clinical test for use in the evaluation of neuromuscular dysfunction.

This material was presented in October at the 14th Annual Meeting of the Society for Neuroscience.

Motor Control in Movement Disorders

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Sponsor: Liberty Mutual Insurance Company and VA Medical Center

Purpose — Since it appeared natural that we apply our ability to decompose the myoelectric signal and to analyze the behavior of individual muscle-fiber discharges to other than normal subjects, we have begun to study in detail the myoelectric signal in patients with movement disorders. We plan to compare the motor-unit contraction properties of such patients with our previously documented findings on normal subjects. We especially want to ascertain differences and similarities in phenomena such as the common drive and the interplay between firing rate and recruitment. Both of these phenomena were discussed in last year's activities report, and the latter phenomenon is addressed above.

Progress — For these studies, we are selecting patients who have well-defined lesions, strategically located in the areas of the brain and spinal cord, that play a crucial role in regulating the output of movement. We hope that the study of such patients will help us to identify and quantify the amount of motor disturbance. To date, we have studied two patients with Parkinson's Disease and one patient with Cerebellar Atrophy, and we have just begun to analyze the data.

Control of Antagonist Muscles

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Sponsor: Liberty Mutual Insurance Company

Purpose — We are attempting to clarify the control mechanism of antagonist (opposing) muscles during the initiation and continued production of force associated with voluntary contractions. Our study focuses on the flexor pollicis longus and extensor pollicis, the two sole activators of the distal thumb joint.

Progress — During the past year, we accumulated additional data and integrated these data with our previous observations. We have also described more accurately the details of the behavior of the motor units in antagonist muscles. Our understanding of this behavior is the same as in last year's description.

Preliminary Results — During pure joint stiffening, the motor units in the two contracting antagonist muscles are controlled by the nervous system as if they constitute a single muscle. Conversely, during alternating flexion and extension

contractions, the two antagonist muscles are reciprocally activated. These observations are consistent with the concept that the central nervous system has two separate control schemes for coactivation and for reciprocal inhibition and that these two schemes may be used in different ways to control the torque or stiffness of a joint. The results also support the notion that the central nervous system does not control motor units individually during a muscle contraction and imply that muscles acting on a joint are not necessarily controlled individually. This information is useful in designing exercise programs for impaired muscles.

Future Plans — Two articles are being prepared for publication.

Control of Synergist Muscles

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Sponsor: Liberty Mutual Insurance Company

Purpose — Synergist muscles act in concert and contribute additive force during a specific function. Since the body's musculature is composed of both antagonist and synergist muscles, it is important for us to complement our work on antagonist muscles with studies of synergist muscle control. We are studying the motor-unit interactions of the extensor carpi radialis longus (ECRL) and extensor carpi ulnaris (ECU). These muscles act to control wrist movement and can function synergistically or antagonistically depending on the task.

Progress — A previously developed technique was used this year to decompose the myoelectric signal detected with a needle electrode from the muscles that were associated with each contraction of each active motor unit. In experiments with normal subjects, we made needle-electrode recordings from the muscles during the generation of isometric forces at the wrist. A computerized data-acquisition-and-control system was used to present trajectories for subjects to track and also was used to control the recording of high-quality myoelectric signals. Extensive signal processing and analysis were performed to examine the motor-unit interactions.

Preliminary Results — The results indicated the following:

1) Small 1-2 Hz common fluctuations with no phase shift in the mean firing rates of motor units were noticed within the muscles studied; this was consistent with earlier work on other muscles. Common fluctuations also exist between the firing rates of ECU and ECRL motor units but with a variable phase shift. The variable phase shift suggests that the muscles are not considered as a functional unit by the CNS during synergistic function.

2) Cross-correlation analysis of the motor unit contraction times of either the ECU or the ECRL indicated that synchronization exists among the motor units within each muscle. No other significant interaction between the trains within a muscle were detected. Cross-intensity analysis performed across the muscles showed no significant interaction between the motor units of the two synergist muscles. The absence of interactions between the muscles further supports the notion of the independent functioning of the muscles.

3) Analysis of the firing rate of motor units active during functionally related

changes from wrist extension to adduction or abduction demonstrated a motor unit discharge behavior which is consistent with a notion indicating a multichannel input to sets of motor units in the two muscles.

Future Plans — All the new data are currently undergoing scrutiny. During the next year, we plan to sift through the data and to prepare some clearer descriptions of the phenomena we have observed.

C. Muscle Fatigue

Muscle Fatigue and the Myoelectric Signal

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Sponsor: VA Medical Center

Purpose — The frequency spectrum of the myoelectric signal detected with surface electrodes changes during sustained muscle contractions. High-frequency components decrease while low-frequency components increase in amplitude. Various studies during the past two decades have searched for the cause of this frequency change and specifically have attempted to determine whether the change originates from the physical properties of muscle fibers, such as their conduction velocity, or originates from control properties, such as firing statistics.

Our investigations of this phenomenon have a twofold purpose: to gain knowledge concerning the process of fatigue within a muscle subjected to continuous usage, and to develop techniques for objectively assessing the fatigue rate of contracting muscles. The latter purpose is particularly interesting because it could ultimately result in a methodology for noninvasively and quantitatively measuring localized fatigue in human subjects. Our continuing hypothesis relates the change in the frequency spectrum of the externally detected myoelectric signal to intramuscular biochemical events that occur as the muscle generates force.

A review article documenting these associations was published by *CRC Critical Reviews in Bioengineering* in January 1985. Two presentations on this topic were made at national symposia in October.

Muscle Fiber Conduction Velocity

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Sponsor: Liberty Mutual Insurance Company

Purpose — In 1983, we developed a new cross-correlation technique for measuring the conduction velocity of the myoelectric signal along the length of the muscle fibers. The technique employs a four-bar electrode and double-differentiated signal output to suppress common-mode signals. In 1984, the technique was incorporated into a plug-in module in the MFM data acquisition system. Now we can more easily analyze and compare measurements of median frequency and conduction velocity.

Progress — Also in 1984, we devised a data-sampling program for the Digital PDP-11 microcomputer so that the myoelectric signal and its conduction velocity and median frequency are presented in a digital display. This will facilitate the storage and graphic presentation of data. In addition, a cross-correlation program to compute the conduction velocity from the sampled data has been developed. With this program, we can measure and compare conduction velocity and median frequency for different electrode locations. Plots of conduction velocity and correlation coefficient as a function of time and electrode position can be produced with this technique. These comparisons enable us to relate anatomical features, such as the location of innervation zones and tendonous portions of muscle, to measurements of the electrical signal. We are now a step closer to interpreting changes in the myoelectric signal that affect measurements of conduction velocity and median frequency.

Future Plans — During the next year, we plan to evaluate the MFM's capability for measuring the conduction velocity of the myoelectric signals in several muscles that are of different size and that have different arrangements of muscle fiber.

Two papers describing our work to date have been accepted for publication, one in the *Journal of Applied Physiology* and the other in the *IEEE Transactions on Biomedical Engineering*.

The Muscle Fatigue Monitor

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Sponsor: Liberty Mutual Insurance Company

Purpose — The portable Muscle Fatigue Monitor (MFM), which we upgraded in 1983, allows us to objectively measure muscle fatigue of subjects in both laboratory and field environments. The computer-assisted MFM automatically measures the median frequency of the myoelectric signal that occurs during a sustained contraction; the signal is detected with surface electrodes placed on a subject's muscle. Changes in the median frequency during a sustained muscle contraction are associated with the muscle-fatigue process. (A detailed description appears in our paper, "Muscle Fatigue Monitor (MFM): Second Generation," which was published in *IEEE Transactions on Biomedical Engineering* in January, 1985.)

Progress — In 1984, to further enhance the MFM, we fabricated a plug-in circuit module to measure the conduction velocity of the detected myoelectric signal. Similar to changes in the median frequency, changes in conduction velocity are strongly associated with a muscle's fatigue process. The additional measurement of conduction velocity therefore can be used for verifying an assessment of muscle fatigue.

We also developed some new and easy-to-use software to coordinate the operation of the median frequency and the conduction-velocity circuit modules. The new software package has been compiled on the VAX 750 computer. Interactive programs have been written to control the MFM, to sample data, and to process eight channels of fatigue-related information. Altogether, this software

enables investigators to perform and evaluate a variety of complex muscle-fatigue experiments. With its hardware modules for measuring median frequency and conduction velocity and its new software package, the MFM is becoming a powerful tool for augmenting our understanding of the underlying processes of muscle fatigue.

Effects of Surface Electrode Location on the Myoelectric Signal Parameters

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Sponsor: Liberty Mutual Insurance Company

Purpose — Our muscle fatigue studies depend upon measurements detected with surface electrodes located above a contracting muscle. Measurements of median frequency and conduction velocity are sensitive to the location of the detecting electrode with respect to distance from the signal source, direction of the signal, and conduction properties of the underlying tissue. Consequently, we must establish criteria for locating the surface electrodes with respect to innervation zones and the tendonous portions of a muscle.

Progress — In order to determine the effect of electrode location on measurements of conduction velocity and median frequency of the myoelectric signal, we studied surface-electrode placement in relation to one muscle's innervation zone and tendonous portions. A series of tests were completed on the tibialis anterior muscle of the leg in 17 normal subjects. For each subject tested, we located the tendonous portions of the muscle and the motor points (the surface projections of the innervation zones). Surface myoelectric signals were recorded during short-term and fatiguing isometric contractions sustained at a constant force of 20 percent and 80 percent of the maximal contraction level. Numerous sites along the length of the muscle were tested and then analyzed by the MFM. In addition, measurements of the conduction velocity of the myoelectric signal along the length of the muscle fibers were computed on the PDP-11 microcomputer. (See above for more on the details of measuring conduction velocity.)

Preliminary Results — The tests indicated that, despite considerable variability in the location and number of innervation zones, the value of the median frequency changes in a consistent and repeatable manner. The force level of the contraction did not affect the changes observed except to uniformly increase the value of the median frequency. The rate of decrease of median frequency was not sensitive to electrode placement. These results were consistent with mathematical calculations formulated in this and other laboratories.

Results for conduction velocity demonstrated a typical pattern with respect to location. The distal, or lowest portion of the muscle provided the most reliable measurements. Although the changes in conduction velocity and median frequency at different locations were generally uncorrelated, the median frequency did increase with conduction velocity when the myoelectric signal was obtained from areas other than near the innervation zone and the tendonous regions. Similar studies are planned for other muscle groups.

This material was presented in October at the 14th Annual Meeting of the Society for Neuroscience.

Myobeeper

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Sponsor: Liberty Mutual Insurance Company

Progress — In the past few years, we have been describing the design and evaluation of the myobeeper, a portable biofeedback device that detects myoelectric signals from the surface of the skin above the muscles. In 1984, we documented our extensive testing of the unit in the busy clinical environments of six major hospitals in the Boston area. The results were favorable, indicating that the Myobeeper is well suited for use in clinical environments.

Our evaluation results appear in a paper published this year by the *Journal of Rehabilitation Research*.

Topical Anesthesia and Muscular Hypertonicity

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Sponsor: Liberty Mutual Insurance Company

Purpose — Some form of muscle rigidity (spasticity) affects at least 6 million people in the United States. The estimated annual cost to our society for health care and the reduction of manpower in the work environment exceeds $20 billion.

Progress — For the past 6 years, we have been experimenting with a noninvasive technique for rehabilitating patients who have suffered from strokes or head injuries. This technique entails applying a topical anesthetic to selected skin areas on the affected limbs. We have observed that these applications are associated with notable decreases in muscle rigidity and often with increased limb mobility. The short-term effects (within 1 hour after application of the topical anesthetic) have been studied in 80 patients; the long-term effects are currently under investigation. To date, we have collected various data concerning kinematic parameters, reflexes, and expressions of functional capabilities on 12 patients. During the past year, we continued to analyze these data.

The physiological mechanisms underlying the observed increase in movement capability are still not well understood. Our previous neurophysiological studies suggested an interaction between mechanoreceptors, or sensory receptors, in the skin and the motoneurons—nerve fibers that control muscle force and stiffness. In order to test the mechanical basis for this neural interaction, we used conventional goniometry to measure the active and passive range of limb movements.

Preliminary Results — The mechanical interaction between opposing muscle groups around a joint was measured by comparing the change in the active and passive range of limb movements. The passive range of movement served as an index for the reduction of muscle hypertonicity, or stiffness, and the active range of movement was used to measure the motor output to the muscle. In a few instances, the active range of movement increased with no change in the passive range, indicating an increased output of the motor system with no measurable reduction in muscular hypertonicity. Also, in a few cases, a decreased reduction of muscular hypertonicity with no measurable change in the motor output to the muscle was recorded. In most of our studies, however, where the upper and lower limb joints were tested for different movements (flexion, abduction, and so forth), a simultaneous increase in the active and passive range of movement was

recorded. These results indicated a concurrent increase in the output of the motor system with a reduction in muscular stiffness. This association of neural influences provides a noninvasive approach for modifying the performance of the motor output in some patients with muscle rigidity.

Our neurophysiological and clinical observations in this area have continued to attract investigators in other institutions. At the 14th Meeting of the Society for Neuroscience, Pozos and colleagues from the University of Minnesota reported that application of topical anesthesia to the lower limb had reduced the amplitude of physiological tremors in normal subjects and had reduced pathological clonus, or involuntary muscle contraction and relaxation, in patients with spinal cord injuries.

A presentation was made in October at the 14th Annual Meeting of the Society for Neuroscience, and two manuscripts are being prepared to further describe these observations.

Muscle Fatigue and Back Pain

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Sponsor: Liberty Mutual Insurance Company

Purpose — During the past decade, new noninvasive techniques for extracting information from surface myoelectric signals have become available, and proven techniques have become more reliable and quantitative. These developments enable us to assess the performance capability of individual muscles as well as groups of muscles.

As many as 75 million Americans now suffer from back problems, and each year seven million more people develop problems. Back problems are estimated to cost a staggering $11 billion each year due to diminished work productivity, and many billions more are spent for medical treatment. Improved methods for assessing back disorders could help to diminish the problems and the financial burden of this disabling condition.

Progress — During 1984, we began to explore the possibility of using our median-frequency technique, along with measurements of conduction velocity, to assess the performance and interaction of the muscles in the trunk. We hope to develop a reliable screening method for distinguishing between the performance of trunk muscles in individuals with and without back disorders.

Future Plans — We will continue this effort by studying the myoelectric signal of several trunk muscles in healthy individuals and in individuals who have experienced episodes of back pain. The signal will be detected through surface electrodes, and accurate measurements will require a special restraining device to reliably stabilize the trunk. The considerable effort anticipated for constructing such a device will assure that the muscle activity observed is actually associated with the flexion or extension torque being monitored.

IX. Ligaments and Tendons

[*See also pg. 199*]

Affects of Immobilization and Motion in the Injured Tendon (Chicken)

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Sponsor: National Institutes of Health

Purpose — Tendon injuries constitute an increasing proportion of trauma cases reported at our hospital, yet research in tendon healing has been neglected. There is a strong clinical impression that exercise speeds healing in an injured tendon. Early motion of the affected tendon favorably influences collagen synthesis and maturation, particularly the quantity of and types of collagen crosslinks formed. The variety and amount of collagen crosslinks present are directly related to the strength and mobility of the healing tendon. Without the appropriate types of crosslinks in the appropriate locations within collagen molecules, connective tissue would literally fall apart. On the other hand, too many crosslinks in joint tissue or tendon can restrict mobility. Since the tensile strength of tendons is dependent on the nature of the collagen, and physical activity strengthens tendons, exercise must favorably alter the crosslink chemistry of healing tendons. Moreover, a study of how cultures of tendon cells react biochemically to stress *in vitro* will indicate how stress *in vivo* acts to strengthen healing tendons.

Exercise Effects on Tendon Repair (Rabbits, Chickens)

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Sponsor: National Institutes of Health

Purpose — The objective of this proposal is to evaluate the tendon repair process by means of a multidisciplinary approach. A variety of exercise conditions will be imposed in order to establish the conditions which will maximize the rate and strength of the repair. Preliminary studies will be performed to evaluate the influence of rigid immobilization, cage activity, farm activity, and vigorous daily treadmill exercise on the size and strength of normal tendons and on the strength of insertion sites into bone. We also will evaluate the influence of these exercise factors on the rate of tendon healing. Of particular importance will be studies on the exercise postoperatively after tendon repair. The purpose of this part of the study will be to determine the conditions which will maximize the quality of repair, including the proper duration of immobilizaton, timing onset of the exercise programmed, and the exercise schedule.

A variety of techniques will be used to evaluate the quality of repair. Correlation studies will be performed between morphologic, bioengineering, and biochemical procedures. Video dimension analysis will be performed under various strain rate conditions including high speed motion analysis converted to the video format. It will be possible to study the repair line and the remainder of the tendon composite independently using this approach. This is necessary because the effects of exercise (or its deficiency) are different between various elements of the tendon composite, viz. area of repair, area of tendon proximal and

distal to the repair site and the tendon insertion site. A variety of biochemical techniques also will be used to correlate with the tensile test measurements. These will include estimation of water content, total hexosamine, glycosaminoglycan, total collagen, soluble collagen, and analysis of reducible collagen cross-links. The application of drugs and hormones known to modify connective tissue metabolism will be explored to determine whether the immobilization effects occurring in the early phase of repair can be overcome without impeding the tendon repair process.

The L.T.W. Connective Tendon/Ligament Device

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Research laboratories interested in the problems associated with tendon/ligament surgery are often confronted with the difficult task of fastening loads and/or loading instrumentation to the tendons and ligaments of cadavers. Research in this area often necessitates subjecting the intact and repaired sutured tendons and ligaments to biomechanical evaluation, determining the ultimate tensil strength of tendons and ligaments, assessing the tensile parameters of healing tendons and ligaments, and physiologically loading joints.

The measurement techniques require the use of connective devices that clamp onto the end of a ligament or tendon. A cable, linkage, or other instrumentation is then attached to the other end of the connective device. The clamping action of the device often damages (at the clamping/gripping site) the fibers within the tendon or ligament to be tested. Consequently, stress concentration and slippage at the clamping site make it difficult to obtain reliable data.

It is essential to don ligament and the loading instrumentation and to avoid damaging fibers with clamping actions that would influence the tensile strength of the material to be tested, as well as to minimize the creation of new areas of stress concentration. The L.T.W. Connective Tendon/Ligament Device meets these requirements as it allows the loading of joints as physiologically as possible.

Pathokinesiology of Anterior Cruciate Ligament Deficiency

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Sponsor: VA Rehabilitation Research and Development Service

Progress — The progress has been good after conquering some difficulties transferring theoretical kinematic concepts concerning helical motion into useful software analyses that apply to locomotion. Presently, the knees of 17 uninjured and seven injured subjects have undergone extensive study of their kinematics and EMG control during walking and pivoting.

Preliminary Results — Several helical motion variables, such as direction cosines and helical rotation, easily distinguish the injured and uninjured knees while the standard anatomic angles do not. A presentation of this technique was made at the International Society of Biomechanics Congress in June 1985. A manuscript for journal publication of these results is presently being prepared. Work is continuing to enlarge the data base and to refine the analysis in order to

further distinguish between loose and tight injured knees. A necessary component of this research has developed which was not anticipated. This is the computer graphical presentation of the results that depict the three dimensional motions. It is necessary for fully appreciating the kinematics and for understandable presentation of the results. Supplemental funds to support this endeavor are being sought through the VA Rehabilitation Research and Development Service.

Future Plans — The EMG patterns of several muscles in the patients with the injured knees are extremely different from the normal during both walking and pivoting. A presentation of these results was at the Engineering in Medicine and Biology Conference in late September 1985. A manuscript describing the full results is also being prepared for journal publication. Again, more subjects are scheduled to be studied in order to increase the data base.

Anterior Cruciate Ligament Healing (Dogs, Rabbits)

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Sponsor: National Institutes of Health

Purpose — The limitations in the healing response of the anterior cruciate ligament (ACL) are well organized. Various reasons have been proposed for the failure of healing of this ligament, particularly mechanical factors and nutritional factors resulting from a limited blood supply. Additional harmful effects to repair the anterior cruciate ligament result from the post-injury synovial fluid which contains numerous proteolytic enzymes harmful to immature proliferating cells and their matrix. In summary, failure of repair is the result of a multifactorial hostile environment.

However, intrinsic repair of flexor tendon in the flexor tendon sheath has been demonstrated in this laboratory when intermittent passive motion is imposed. This environment is seemingly as "hostile" as in the case of the ACL. The blood supply and nutrition are outwardly as limited. Why is intrinsic healing so effective in the case of the tendon, but so limited in the case of the ACL?

These investigators propose a study to evaluate the early ACL healing response and to compare it to the process of flexor tendon healing. A series of descriptive studies are proposed to clarify differences between the ACL and other ligaments of the knee joint, as well as between flexor tendon with respect to routes of nutrition, repair mechanisms, and the influence of activity on repair rate and quality.

Future Plans — Subsequent studies will evaluate the routes of nutrition of tissues used in ACL reconstruction, the potential for augmentation of that nutrition by the anterior synovial fat pad, the collagen turnover rate of ligament autocraft replacements, and the changes in their strength characteristics with time. Nutritional studies will employ labelled collagen precursors (L-5-3H proline) administered by routes chosen to elucidate the questions of nutritional mechanisms. Turnover studies will employ chronic collagen prelabeling. Evaluation of repair mechanisms will employ a variety of morphological, biomechanical, and biochemical techniques.

Evaluation of Tubular Internal Fixation Plate for Fracture Management

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The overall objective is to determine whether significant advantages can be obtained from internal fixation of diaphyseal fractures using plates with improved design. Our goal is to test the newly developed design criteria, i.e. moderate bending and torsional plate rigidities needed for early immobilization in order to achieve fracture healing without bone shortening and/or angulation. Low plate axial rigidity is desirable to minimize stress (strain) shielding of the underlying bone during the post-union remodeling process. A new plate with a tubular cross section is made of stainless steel filled with polyethylene. This plate has rigidity characteristics and will be used in a canine unilateral midshaft femoral osteotomy mode. A traditional solid stainless steel plate of identical external geometry will be used in a separate series of animals with similar osteotomy. In addition, it is also our goal to test whether such a low axial rigidity plate can prove to be advantageous to the recovery of full structural properties of the underlying bone following plate removal.

Progress — The evaluation of the bone lying beneath both the traditional solid stainless steel (control) and the new tubular (experimental) plates is being performed now using X-ray, geometric measurements, histomorphometric measurements, and biochemical techniques. A comparison is being made specifically between the actual physical properties of bone and the structural and mechanical properties obtained by biomechanical bending and axial and torsional testing. Histomorphometric data have shown on the average that bone porosity is higher for the control solid stainless steel plate while there is an increase in new bone growth and less porosity for bone lying beneath the experimental hollow plate. This information correlates well with the bioengineering tests performed. With further comparison and study of these test results, we hope to provide more insight into the problem of localized osteopenia with the use of internal fixation plate systems.

Structural and Functional Properties of Normal and Repaired Ligaments

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The objective of this research is to evaluate the ligament repair process in a model synovial joint system. A variety of activity conditions will be used in order to determine which set of conditions will maximize the speed and strength of the repair or healing of ligaments. To achieve this objective, it will be necessary to determine the influence of a wide range of physical factors such as rigid immobilization, cage activity, normal activity, intermittent-controlled passive motion, and rigorous daily exercise programs on the size and strength of normal and repaired/healing ligaments. The timing of the onset of these forces at the repair line and its magnitude and frequency need to be optimized in order to achieve the most rapid and complete remodeling of the repaired/healing ligaments.

Progress — To date, we have studied medial collateral ligament healing with and without surgical repair using a canine model. The evaluation of the quality of ligament healing and repair has included correlative studies using morphologic, biomechanical, and biochemical techniques. Specifically, we have studied healing ligaments subjected to various regimens of repair and early mobilization over a 6-week time period. We have focused on the biomechanical properties of the ligament repair site and the areas of the ligament proximal and distal to the repair. The structural and mechanical properties obtained were compared to the biochemical results and histological appearance of each of these areas.

Future Plans — We are currently performing experiments over a 12-week time period to further define proper clinical regimens that may be used to provide better healing of ligament structures. Our goal is essentially two-fold: to improve the structural integrity of the healing ligament to ameliorate problems of knee joint instability, and to improve the material properties of the healing ligament substance as well.

X. Arthritis

Biofeedback and Relaxation Training as an Adjunctive Treatment for Severe Rheumatoid Arthritis: A Preliminary Investigation

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Purpose — Most studies on rheumatoid arthritis (RA) to date have focused on the issues of diagnosis and personality factors, rather than any potential adjunctive treatment procedures. Further, treatment procedures that fail to attend to underlying physiological factors (i.e. psychotherapy) have reportedly met with little success. The few studies that consistently report improvements have utilized a combination of relaxation, thermal biofeedback, or other self-regulation strategies. However, no direct attention has been afforded the more chronic, severe RA patient and the potential gain of such procedures with these persons, the role that relaxation may be having in the treatment apart from the effects of biofeedback, nor how the actual sites of greatest inflammation are affected by these techniques.

Progress — Four male patients (mean age 48.8 years) from the VAMC-Albany's Rehabilitation Medicine Service were obtained through physician referral for inclusion in this study. Three of the subjects were diagnosed as suffering from Stage III RA (American Arthritis Foundation criteria), while the fourth was similarly diagnosed as having Stage II RA. Mean history of the disorder was 10.4 years.

Subjects were interviewed during an initial intake evaluation where they were informed of the purposes and procedures of the study. Each subject then completed a battery of psychological tests, which included the MMPI, STAI, BDI, and the Multidimentional Health Locus of Control. Additionally, range of motion, muscle strength in affected areas, and grip strength measures were obtained. Subjects were also asked to estimate the mean number of awakenings per night due to pain and duration of morning stiffness.

Following pretreatment evaluations, subjects were randomly assigned to 1-, 2-, and 3-week baseline periods, during which time they were seen on a twice weekly basis to gather EMG and temperature readings. EMG readings were from the non-dominant forearm and medically diagnosed the most inflammed joint. Temperature was recorded from the left forefinger. Patients were also requested to keep thrice daily pain ratings during baseline and treatment; these were done on a 0 to 100 scale (0 = "no pain", 100 = "worst imaginable pain").

Treatment sessions were conducted in a sound-attentuated, air-conditioned chamber and consisted of 1) initial discussion with the therapist of treatment progress and adequacy of home practice; 2) a 1-minute integrated baseline EMG (two sites) and temperature reading; 3) a 15-minute instruction in passive muscle relaxation augmented with autogenic phases; 4) a 4-minute return to baseline condition (with EMG and temperature readings); and 5) a 15-minute instruction

and practice in temperature augmentation biofeedback. Treatment sessions generally took place on a twice weekly schedule, though timing of sessions was sometimes modified to accommodate patients schedules.

Preliminary Results — One subject completed 12 sessions, one subject 10 sessions, and two subjects only five sessions. One became involved in outside treatment and dropped from the study. Another reportedly dropped out due to the aggravation of his pain from the requisite driving to the hospital. Each of the subjects completed post-treatment measures. Results suggest that increased hand temperature was not related to decreased pain ratings or increased physical functioning. Rather, the EMG readings suggested that increased relaxation may well be the more important factor accounting for improvements in chronic RA patients. There was no apparent direct relationship between EMG readings from the most inflammed joint and the nondominant forearm. While a complicated pattern emerged, most psychological measures of all patients showed a positive relationship to ratings of improvement by the patient and investigators.

The results of this preliminary investigation suggest that the gains for the chronic, severe RA patient are more modest than those reported in the literature. Further, the improvement seems tied to an increased ability to effect a muscular rather than a vascular alteration. The psychological factors of "renewed hope" and ability to impact on a "hopeless" condition were suggested, as was improved psychological functioning following treatment.

The Use of Biofeedback in the Adjunctive Treatment of Rheumatoid Arthritis: Components of Change and Underlying Psychophysiological Processes

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Sponsor: VA Medical Center and State University of New York—Albany

Purpose — The major idea to be developed will be the investigation of active and necessary treatment components in a non-pharmacological, adjunctive treatment of severe rheumatoid arthritis. The impact would be to identify what components within previously investigated treatment methods were most effective as determined by treatment outcome measures, and what effect, if any, these methods had on underlying immune system changes.

This study would investigate in a controlled manner, the singular impact of previous treatment methods on similar treatment outcome measures. Rheumatoid arthritic patients would be matched and assigned randomly to one of three treatment groups, or a waitlist control group. Treatment would involve receiving either thermal biofeedback, relaxation training, or cognitive therapy. Pre- and post-treatment measures will include appropriate laboratory tests to investigate T and B cells, and all treatment measures determined to be appropriate from earlier investigations will be continued to determine overall effectiveness. Follow-up evaluation would be necessary to measure the long-term impact of treatment and to rule out the cyclical improvements found in this particular disease.

This study holds two important factors that need consideration before development of a proposal. First, the T and B cell laboratory values require an expensive laboratory procedure at present, and would require additional support

to become possible, as would the necessary staffing to further the development and clarification of biofeedback as an effective treatment component for the large group of rheumatoid arthritics. Second, a recent study suggested that, in order to find appropriate subjects for inclusion in the study, it may become necessary to open the subject pool to the local community rather than a strictly veteran population. However, the impact of the study would have direct and considerable application to the veteran population served both in this medical center and nationally.

Future Plans — By 5 years, successful completion of this study and long-term follow-up will have demonstrated the long-term effectiveness of this type of intervention, and established its appropriate place within a treatment regimen for the rheumatoid arthritic veteran.

Illness Cognition and Coping in the Elderly (Human)

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Sponsor: National Institutes of Health

Purpose — The proposed studies use multi-dimensional scaling and open-ended interviews to uncover the content and underlying dimensions of elderly people's illness cognition, i.e., the cues they use to identify specific illnesses and their ideas about the cause, time line, and consequences of illness. The procedures will also tap how they respond emotionally to illness and how they cope with it. Scales will be developed to measure these factors in clinical populations so we can compare elderly and middle-aged respondents and patients to one another and to patients with four different chronic diseases (hypertension, COPD, arthritis, and cancer in remission). We will study how illness cognition affects emotion and coping, how all three affect selection of symptoms for reporting at clinic visits, how the three affect confusions between different illnesses, and how they influence compliance with treatment for problems presented by the patients in comparison to unreported problems uncovered by the practitioner. We will assess whether patients misidentify the nature and cause of illness because their expectations regarding symptom presentations are appropriate to the natural history of disorders in the middle rather than the later years of life.

The final goals are to see whether illness representations and coping are related to feelings of age and to the development of dependency and to unnecessary physical and psychosocial disability. Seeing illness as progressing uncontrollably with age may provoke loss of hope and depressive feelings and lead to apathy and withdrawal from social relationships. These hypotheses will be tested in the four clinical populations of elderly patients.

Finally, an intervention study is proposed comparing a participatory interaction with a standard treatment control. The participatory interaction is designed to enhance the patient's perception that he/she is an active agent in the identification and treatment of illness problems and to increase his/her feeling of competence, reduce his/her sense of psychological age, and generalize improved coping skills to everyday problems so as to reduce physical and psychosocial disability.

Impact of Arthritis Self-Care Programs for Rural Persons

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Sponsor: National Institute for Handicapped Research

Purpose — Chronic diseases such as arthritis are often inadequately managed by the health care system. The intent of this research is to develop an effective and efficient supplement to the existing health care services provided for persons with arthritis, especially those residing in rural areas. The specific aims of the research are to clarify the circumstances under which self-care education and social support, natural/informal and contrived/formal, influence changes in the knowledge, behavior, function, depression, and pain of persons with arthritis who reside in rural areas of western and southwestern Virginia.

Progress — The study uses an experimental design. Subjects, adult volunteers with verifiable rheumatic diseases, will be assigned randomly to the experimental conditions. The experimental conditions are: 1) an individualized self-care program; and 2) a small group self-care program. The education component will be standardized across the experimental conditions. All subjects will eventually receive some form of self-care education. The social support component will vary across the experimental conditions and will include contrived/formal components that will be adapted to the self-care learning needs of a rural population. The efficacy of intervention will be assessed periodically over an 8-month period. The effects of natural social support, demographic variables, medical diagnosis, and duration of disease will be controlled. The data will be analyzed through a variety of univariate and multivariate methods. Non-parametric methods will be used when necessary.

The research will be conducted by an interdisciplinary team consisting of a nurse-sociologist, community psychologist, rheumatologist, statistician, anthropologist, and nurse-health educator.

Preliminary Results — Work completed to date includes: 1) an assessment of the educational needs of rural persons with arthritis; 2) a self-care curriculum and six tapes and six booklets containing the curriculum; 3) pre-tests of the psychometric properties of several research instruments; 4) development of our instrument set; and 5) numerous scientific and community (key) presentations.

Arthritis Rehabilitation Unit

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Sponsor: National Institute for Handicapped Research

Purpose — The Arthritis Rehabilitation Unit (ARU) consists of 5 beds on an existing 22 bed rehabilitation unit in the Towers Building at the University. The Rehabilitation staff consists of a rheumatologist, orthopedic surgeon, physiatrist, rehabilitation nurses, occupational and physical therapists, social workers, psychologists, and health sports and rehabilitation counselors.

Progress — To date, over 104 patients have been admitted to the rehabilitation program. The primary diagnosis is rheumatoid arthritis, although patients with

other diagnoses such as degenerative joint disease, juvenile rheumatoid arthritis, and ankylosing spondylitis are admitted. Demographic information on the patients shows that the mean age is 62, mean disease duration is 14 years, mean education level is 10th grade, and a number of these people have concurrent medical conditions which can complicate the rehabilitation program.

The staff of the Arthritis Rehabilitation Unit is using the Arthritis Impact Measurement Scale, an outcome measure developed at the Boston University Multipurpose Arthritis Center, to assess patients on nine scales: mobility, physical activity, dexterity, household activity, social activity, ADL, pain, depression, and anxiety. Three-month, 6-month, and 1-year follow-up data are collected on all of the patients at the rehabilitation unit to help determine the long-term benefits of the rehabilitation program.

Training efforts have included a nursing program in arthritis for the rehabilitation nurses on the unit, a physical therapy consultant to discuss management of musculorskeletal problems in arthritis for the entire staff, and a statewide program for public health nurses in rehabilitation of patients with arthritis.

The current projects at the Arthritis Rehabilitation Unit include a rehabilitation survey of more than 500 rehabilitation units to help determine the scope of arthritis rehabilitation in the U.S. and the need for staff training in management of arthritis patients. The ARU staff has also been engaged in a cooperative effort with the Virginia Division of Rehabilitative Services to place a part-time vocational counselor in the Arthritic Clinic and make available a program evaluator to interview patients. Information is gathered on their employment status or disability status to determine the extent to which people with arthritis are placed on disability and the extent to which rehabilitation services are utilized.

Investigations of Osteoarthritis and Bone Loss

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Sponsor: National Institutes of Health

Purpose — Osteoarthritis and bone loss are the two principal age-related changes of the human skeleton. Even though these changes are considered inherent to aging, they may result in incapacitation ailments. Bone loss and osteoarthritis are universal phenomena. The advanced cases of osteoarthritis (degenerative joint disease) produce severe restrictions of movement associated with pain. Advanced bone loss may result in osteoporosis and frequent bone fractures. At some time during the fourth decade of life the human skeleton begins to loose bone. That is, bone mass decreases in relation to bone volume. In tabular bones, bone is resorbed from the endosteal surface. Because of the thinning of the cortical bone shell, bones lose their mechanical integrity and fracture more readily. The trabecular bone mass of the vertebral column also decreases with age. The vertebral plates decrease in density, lose resistance to vertical compression stress, and are more vulnerable to vertebral collapse. Most prominent are vertebral compression fractures and fractures of the femoral neck. The following skeletal sites are involved in the present study: hand-wrist, ulna and radius, and vertebral column.

Progress — This project deals with the epidemiological, genetic, and longitudinal aspects of osteoarthritis and bone loss among the following: 1) the participants of the Baltimore Longitudinal Study; 2) in a sample of normal children and adult Guamanians (Chamorros); 3) among patients afflicted with Amyotrophic Lateral Sclerosis/Parkinsonism Dementia Complex of Guam; and 4) in a study of bone mineral density and effect of muscular activity on bone in rats.

Ferrographic and Biochemical Analysis of Wear Particles in Human Joints

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Sponsor: VA Rehabilitation Research and Development Service

Progress — Our first short-term objective in the presently funded proposal was to identify those components of cartilaginous wear particles that produce cellular activation and contribute to arthritic changes. Investigation involving tissue culture experiments *in vitro* and animal studies *in vivo* have confirmed the importance of cartilage proteoglycans as mediators of inflammation and arthritic changes. Recent estimates of the proteoglycan content of human synovial fluid during rheumatoid and osteoarthritis are compatible with the hypothesis that our experimental findings reflect the pathophysiological condition of human arthritic joints.

The second short-term objective, to evaluate catabolin release in response to wear particles, has also been met. As we saw for collagenase, synovial cells secrete more catabolin when challenged with wear particles.

Preliminary Results — Finally, we are continuing to look at further selected patient groups by synovial ferrography, as planned. Particular attention is being applied to rheumatoid fluid, which has hitherto received little analysis by ferrography. Our preliminary studies show that ferrograms prepared from rheumatoid synovial fluids are strikingly different from those prepared from the fluids of non-rheumatoid joints. Wear particles are few in number, but a heavy precipitate of magnetized cells is recovered.

Multipurpose Arthritis Center, Northwestern University

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Northwestern University
Chicago, IL 60611

Sponsor: National Institutes of Health

Purpose — This proposal engages scholars and scientists from various schools and departments of Northwestern University and from the community in a comprehensive arthritis program. Five feasibility projects are proposed: cell cytotoxicity in rheumatoid arthritis; phenytoin modulation of collagen and collagenese synthesis in synovial cells and effect on macrophages; connective tissue constituent immunogenicity in juvenile chronic arthritis; synovial pathology in early osteoarthritis; and analysis of osteoarthritic and rheumatoid bone for use in prothesis design. These projects will support new young scientists as well as allow three senior scientists to extend or redirect their work.

The second area of focus is an interdisciplinary educational program, utilizing a problem solving approach, aimed at both professionals and patients. The three projects proposed are: train and evaluate rheumatology fellows as teachers of

medical residents using a new curriculum to be developed in outpatient musculoskeletal disease; evaluation of a problem-oriented, aerobic-like exercise program for arthritics; and the use of a discussion group format to enhance problem solving skills in the older osteoarthritic. The interdisciplinary team includes professional educators, a medical education evaluator, and health professionals at the medical school.

The third area of focus, community and health services research, draws upon a strong base of community involvement combined with the research excellence of Northwestern's Center for Health Service and Policy Research (CHSPR). Three interrelated projects explore various aspects of knee pathology. The first will develop and validate a measure of outcome for a subsequent comparative study. The second will examine the costs of treatments for osteoarthritis of the knee. The third builds upon the work of the earlier two to compare costs and efficacy of arthroscopic surgery and alternatives. Three additional projects add breadth to the research agenda focusing upon musculoskeletal impairment in the elderly, status of families with juvenile arthritic children, and a multi-center study of Social Security payment allocation systems.

The Biostatistics and Data Management Core will provide individual project technical assistance as well as database management for a computerized case-finding patient index.

Robert B. Brigham Multipurpose Arthritis Center

Matthew H. Liang
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Boston, MA 02115

Sponsor: National Institutes of Health

Purpose — This grant is requested to develop three areas of special interest. The first is applied research in which we aim to: 1) develop a necessary and sufficient database for the rational planning of health services to arthritics; and 2) develop and evaluate model components of cost-effective health care delivery for arthritis patients. We propose to develop and critically evaluate a 7-day rehabilitation work schedule; a model health care system for arthritis disability; stepped-up rehabilitation services to homebound patients; a system of follow-up of rheumatic disease patients discharged from a tertiary care facility; a patient-oriented strategy to improve clinical outcomes; and an educational strategy for the primary prevention of low back injuries in the workplace. As one of the four major joint replacement centers in the world, we propose to evaluate the cost-effectiveness of joint replacement by a multi-dimensional outcome assessment. We seek to document the economic burden to arthritics and the shortfalls in the present health care reimbursement scheme. We propose to evaluate the means by which interventions can be evaluated by comparing the relative merits of existing health status functional instruments.

The second priority is the development of a Core Unit for quantitative research methods, Clinical Epidemiology, and Evaluation Research, which would overlap with many activities of the center and would aid the process of training and establishing investigators. The unit would support at least 10 projects from the day-to-day management of special disease registries to clinical studies directed at improving clinical strategies and decision-making in rheumatology, as well as improving applications of basic research.

Finally, we propose pilot studies in a neglected area of research, the management of severe rheumatoid arthritis patients who have failed all conventional therapy. This will involve the protocols addressing the critical evaluation of total nodal irradiation therapy and leukapheresis therapy of refectory rheumatoid arthritis.

UCSF Multipurpose Arthritis Center

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Sponsor: National Institutes of Health

Progress — The Multipurpose Arthritis Center conducts a broad range of activities in each of three areas—education, community programs, and research. A strong basic research program includes studies in the underlying mechanisms of the rheumatic diseases, particularly immunological mechanisms. Almost all of this research is supported by sources other than the center grant. Among the activities directly supported by the current grant highest priority is given to education, particulary education of primary care physicians, nurses, and allied health professionals. Our objective is to improve the knowledge and skills of students and practitioners of these disciplines in caring for people with arthritis.

High priority is also given to research on a variety of issues in the delivery of health care to people with arthritis. The objective of this research is to construct a database on topics such as the distribution of rheumatology manpower, the costs and utilization of health services, and the causes and consequences of work disability, and to analyze the data for its implications for public policy.

The center also conducts programs in patient and public education and is both an advocate in the community for people with arthritis and a source of authoritative information about the special needs of this group.

Multipurpose Arthritis Center, Downstate Medical Center

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Sponsor: National Institutes of Health

Purpose — Downstate Medical Center with the support of the NIH-sponsored Multipurpose Arthritis Center Grant has been studying various aspects of rheumatology education, research, and community health care in Brooklyn. Through year two, we have had three components (research, education, and community services.) In year three, there are no research components. 1) Our education component is the largest of our center grant and involves the training of medical students, housestaff, primary care physicians (in-patient and out-patient) and nurses in the hope of influencing the care of patients with arthritis-related conditions. An in-depth cost/benefit analysis is being undertaken to determine if such training is beneficial, cost effective, and what modifications in our present system of educating groups of health professionals need to be done. The level of care of the patients involved with groups of health professionals will increase. 2) Another component is our community services. We are attempting to determine the factors that influence a patient with an arthritis-related condition to choose an entrance into the health system. Some choices are more beneficial, more ex-

pensive, and more harmful than others. If the factors concerning the utilization of our health care system are determined, we then can modify them to deliver better, more cost effective health care. We have set up several "self-help" groups to study the nature of patients with rheumatologic disorders. Are these groups similar to or distinctly different from other self-help groups with chronic disorders?

Another project involves a comparison of care by rheumatologists and primary care physicians for patients with similar rheumatic diseases. Year three of our Multipurpose Arthritis Center Grant involves completing data collection; we have developed and are utilizing a number of questionnaires developed by us (and shared with other centers), chart auditing, and computer techniques for categorizing and evaluating the data.

Multipurpose Arthritis Center, University of Missouri

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Sponsor: National Institutes of Health

Purpose — We propose the following objectives under Education and Training: 1) training of arthritis specialist professionals to become educators; 2) providing high quality continuing education programs for all professionals; 3) developing improved curricula in musculoskeletal disease for undergraduate and graduate education of primary care professionals; and 4) studying the effect of patient education and team care in knowledge, attitudes, and behavior in rheumatoid arthritis.

The research objective is to determine if a computer-assisted program can increase the efficacy of the expert rheumatologist to influence favorably the medical management for arthritis patients.

The Community Program objective is to: 1) determine the needs of various communities as related to arthritis; 2) plan programs best suited to meet these needs; and 3) conduct community demonstration programs in public and professional groups.

Methods will include questionnaires on information, attitudes, and behavior; computer analysis; regional and national conferences; team visits to communities; and personal participation in a multidisciplinary team approach to patient care in arthritis.

Multipurpose Arthritis Center, University of Connecticut Health Center

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Sponsor: National Institutes of Health

Purpose — The NIH Multipurpose Arthritis Center is currently funding four major educational efforts. The computer-assisted patient education project has completed a successful program for patients and their families with rheumatoid arthritis. This has been well received by patients and is currently undergoing testing by both patients and their families. Editing of the program will proceed along with the evaluation process. The physician-assisted program has completed a longitudinal study in which physicians are in contact with patients with rheumatoid arthritis over a period of 7 years. This is being evaluated by various

types of physicians and by medical students. Editing of the program will continue as the evaluation proceeds. Another program involves developing methods for teaching Family Medicine Residents, and during the next year more data will be available and the testing methodology improved. Another program involves teaching methodology and content development in the area of physical therapy. Undergraduate teaching of rheumatology by our NIH Multipurpose Center-funded physical therapist educator is now in progress and will be evaluated during the coming year.

The research project on C3 phenotypes has led to interesting findings, such as juvenile onset systemic lupus erythematosus patients have a higher incidence of one phenotype than adult onset patients. Patients with other rheumatic diseases are currently being evaluated. The Administrative Unit is functioning adequately for the Center.

Multipurpose Arthritis Center, Boston University

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Sponsor: National Institutes of Health

Purpose — This proposal describes a detailed plan to expand and strengthen the Boston University Multipurpose Arthritis Center (MAC). A program of activities and specific projects will be pursued in three major components: Research, Education, and Community/Health Services Research. The proposal also describes a plan to support areas of special research interest by means of two Core Units, and to continue an effective Administration Component.

The Research Component will build on a strong base of work funded from other sources. In addition, four Developmental and Feasibility studies are proposed: 1) a study of vitamin A metabolism in prealbumin forms of amyloid disease; 2) the isolation of cDNA clones for serum amyloid A; 3) an investigation of stair climbing in arthritis; and 4) a study of the difficulty dimension in functional assessments.

MAC education efforts will continue to be aimed at a broad spectrum of arthritis health professionals in conjunction with the Schools of Medicine, Nursing, and Allied Health Professions of Boston University. Specific projects in the education component will include an evaluation of the current status of house officer education in rheumatology at internal medicine and family practice residency programs, a study of the effects of a targeted training program on interpersonal skills of physical therapy students, and an investigation of coping in chronic arthritis.

Activities in the Community/HSR component of the MAC will continue to focus on the inner-city community in conjunction with the Department of Health and Hospitals of the City of Boston. Seven specific community/health services research projects are proposed: 1) a project to modify the Arthritis Impact Measurement Scales for use in clinical practice; 2) a project to develop a computer-based community network for clinical rheumatology trials; 3) an inner-city nursing home project combining outreach and data collection for this important population; 4) a study of the rheumatology referral behavior of general internists and family practitioners; 5) an epidemiologic study of osteoarthritis in conjunction with the Framingham Heart Study; 6) an epidemiologic study of oral

contraceptives and rheumatoid arthritis in conjunction with an established drug epidemiology group; and 7) an investigation of the relationship between stressful life events and disease activity in rheumatoid arthritis.

Two Core Units are proposed: an Amyloid studies Core Unit and a Research and Evaluation Support Core Unit. These Core Units will support numerous investigations in areas of special interest to this Center.

Multipurpose Arthritis Center, University of Alabama at Birmingham

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Sponsor: National Institutes of Health

Purpose — The Multipurpose Arthritis Center (MAC) of the University of Alabama in Birmingham (UAB) is a multidisciplinary effort by faculty and staff of the Schools of Medicine, Dentistry, Nursing, Public Health, and Community and Allied Health, as well as the University Hospitals and Clinics. A broad spectrum of ongoing and proposed activities focuses on basic and clinical research, education, community activities, and health services research.

Research in MAC includes studies in the areas of immunology, virology, mycoplasmology, molecular biology, genetics, connective tissue biochemistry, and clinical rheumatology. The Education Component spans the spectrum of professional, allied health, postgraduate, and public and patient educational activities. The Community and Health Services Research Component highlights socioeconomic factors that influence the well-being of patients with rheumatic disease.

This application includes feasibility proposals in fundamental research from seven investigators to study basic mechanisms involved in the pathogenesis of the rheumatic diseases. Five new projects are proposed in patient and professional education. Six projects are proposed in the Community and Health Services Research Component, including critical evaluation analyses applicable to this important area. In addition, three Core Units are proposed—continuation of the Hybridoma Core Facility, development of a new Immunogenetics Core, and a new Evaluation, Biostatistics and Data Management Core Unit.

The overall goals are to coordinate existing arthritis programs and initiate new programs in arthritis so that we can achieve 1) greater knowledge of the etiologies, pathogeneses, and therapies of the rheumatic diseases; 2) better systems of health education; 3) documentation and improvement of future patient services; and 4) a more enlightened community attitude toward arthritis.

Multipurpose Arthritis Center, Indiana University-Purdue University at Indianapolis

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Sponsor: National Institutes of Health

Purpose — The Arthritis Center at the Indiana School of Medicine (IUMPAC) is comprised of components for (a) research, (b) education; and (c) community programs. The research component supports basic studies on connective tissue biochemistry, control mechanisms in connective tissue metabolism, pathogenesis of osteoarthritis, immunologic tolerance, amyloidosis, the effects of immunologic mediators on muscle physiology, and joint biomechanics. In addition, it

encompasses clinical investigations in such areas as post-intestinal bypass arthritis, polymyositis, amyloid disease, and hypogammaglobulinemia.

The education component augments rheumatology training of fellows, house officers, medical students, Allied Health Professionals (AHPs), and patients. Particular emphasis is directed toward improving the training in rheumatology of house officers who aim ultimately to practice as primary care physicians. A Nurse Educator will serve as a liaison between the Rheumatology Division and the Baccalaureate, Graduate Nurse, and Specialist Degree programs in the School of Nursing. A Pediatric Rheumatology Paramedical Team (supervised by an IUMPAC-trained pediatric rheumatologist) is being established, and education in juvenile rheumatoid arthritis will be emphasized at all levels.

The community program will ink IUMPAC with private and governmental health organizations. It will evaluate the efficacy of an AHP Team in providing long-term care. The impact of the team approach on function, disease activity, and psychosocial adaptation is being assessed. Use of informational support groups for patients with rheumatoid arthritis, spondylitis, and lupus will be expanded and efficacy of the groups assessed. Outreach clinics, staffed by a rheumatologist and AHPs, will be established in communities in which specialized expertise is now lacking. Also, a system for regionalization of health care for children and adolescents with arthritis, utilizing community-based AHPs, (Project COUPLE), is planned.

University of Michigan Multipurpose Arthritis Center

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Sponsor: National Institutes of Health

Purpose — This proposal sets forth a plan for further development of the University of Michigan Multipurpose Arthritis Center (UMAC). Osteoarthritis (OA) is to receive special emphasis in the pilot research area and in a major epidemiologic study. The overall objectives of UMAC continue to include: 1) basic and clinical research dealing with the pathogenesis and treatment of the several rheumatic diseases; 2) continuation of education/training programs for physicians and other health professionals to meet the academic and patient care needs in the field; 3) development of new education programs for specific target groups; 4) expansion of a unique program of community-based education for primary care physicians; and 5) evaluation of each education effort by the best available methodology. Established research programs will be complemented by nine new pilot research projects that deal with a new animal model of OA, biochemical mechanisms in OA, new imaging techniques relevant to OA, three different studies of immune cell receptor function, HLA-DR phenotypes in juvenile arthritis, and a virus-induced murine model of polymyositis. Six new educational projects target teachers in the field of physical education, University students with rheumatoid disease, adults with rheumatoid arthritis, primary care physician trainees, juvenile arthritis patients in the public school setting, and assessment of rheumatoid patients with boutonniere deformities treated by nonsurgical means.

In the community programs component, a new study of critical factors that determine primary care physician involvement in continuing medical education

(CME) in the field of rheumatology is proposed. It will utilize previously collected CME data and also determine how new information reaches the primary care practitioner. The population of Tecumseh, Michigan will be re-examined to measure the incidence, regression, and progression of osteoarthritis and osteoporosis as compared to findings 20 years previously (1962-65). A random probability sample of the entire state of Michigan also will be studied to provide estimates of these two conditions in the general population and to identify possible intervention strategies. These research, education, and community projects will be supported by an Administrative Unit that is integrated into the established organization of the University. A special Tissue Culture Core Unit is proposed for continuation since it supports several of the established research programs within this Center. UMAC has the external support of private and state agencies, as well as the required institutional, professional, physical, and patient resources to achieve its stated objectives.

A National Arthritis Data Source (ARAMIS)

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Sponsor: National Institutes of Health

Purpose — ARAMIS (the American Rheumatism Association Medical Information System) is a rheumatic disease computer data bank system containing longitudinal clinical data for approximately 19,000 patients and 120,000 patient encounters. ARAMIS represents more than 100,000 patient-years of observation. The system operates from an IBM 370/3081 computer at Stanford University and is accessed nationally through TYMNET or TELENET communications networks using the Time-Oriented Data Bank (TOD) data management system.

The program is based upon the premises that chronic diseases have become the most prevalent health problems, that study of such diseases requires observation of occurrences over prolonged time periods, that the expense of longitudinal study requires use of economies of scale, that patient outcome in chronic disease results from a complex interplay between multiple factors, and that many important questions need to be studied with observational, in addition to experimental, techniques. This program has the goal of improving knowledge, management, and patient outcome in arthritis by providing long-term information relating disease severity, patient characteristics, social factors, and treatment to patient outcome. The program has two major aims; first to continue to develop a national data resource of high quality, longitudinal, accessible clinical data, and second, to employ these data in a systematic, multicenter investigative program of major clinical questions in the rheumatic diseases.

Program priorities include the classification and definition of diseases, the systematic study of long-term (6 to 20 year) outcomes, the economic impact of illness and treatment, and the study of regional and national differences. Thirty clinical investigators and epidemiologists at 12 institutions undertake over 50 projects annually. The present proposal includes classification studies of osteoarthritis, rheumatoid arthritis, vasculitis, and systemic lupus erythematosus; economic impact studies in each major disease; comparative studies of arthritis at different sites; population-based studies of incidence and prevalence; and long-

term studies of outcome in rheumatoid arthritis, juvenile arthritis, scleroderma, systemic lupus, osteoarthritis, and following joint surgery. With this project, 15 years of data development at numerous institutions are brought to bear upon major clinical questions, and very large and detailed longitudinal patient data sets are made nationally available.

Northeast Ohio Arthritis Center Support

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Sponsor: National Institutes of Health

Purpose — The long-term objectives of this proposal are: 1) to expand efforts directed towards the education of health professionals, patients, families, and the general public; 2) to develop, implement, and evaluate proteotype community/health services programs at a high level of scientific endeavor; and 3) to expand clinical and basic research efforts. New programs in education include 1) an evaluation of use of the education-influential in teaching rheumatology to family practice training units; 2) studies of continuing graduate medical education in arthritis with emphasis upon involvement of the learner in the identification of objectives; and 3) augmentation of an audiovisual library as an umbrella educational resource. Specific new community programs include 1) a systems analysis of arthritis health care delivery in Northeast Ohio; 2) identification of the legal needs of arthritis (chronically ill) patients; 3) studies of the perceived needs of arthritis patients, and available resources to meet those needs as viewed by the patient and community health nurses; 4) the establishment of an industrial data-base pertaining to arthritis problems and management in Northeast Ohio; and 5) an evaluation of NEOMAC/community organizational behavioral interrelationships.

Research programs are targeted to study cartilage metabolism and osteoarthritis, mediators of inflammation, acute phase reactants, the immune response in arthritis, genetic/clinical interplays in ankylosing spondylitis, and myopathic disorders. Core programs include a cell/tissue culture unit and an evaluation/education core as an overall resource to Center project components. Administration includes administrative policy, executive steering (operations), and community advisory committees to fully interdigitate Center/University/Community interface.

XI. Low Back Pain

[*See also pgs. 204, 207, 241*]

Low Back Pain Prevention, Rehabilitation, and High Risk Inventory Development

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Sponsor: National Institute of Handicapped Research

Purpose — The Employee Back Program has established a curriculum that was used with approximately 240 hospital employees. Definitive changes in the employee's education about back care, exercising to promote fitness, and use of these management techniques were documented. The problem with the low-base rate of back injury in the current hospital setting prompted the distribution of our program for wider study to a national hotel chain and perhaps to a national health maintenance organization. The residual program will be continued under the hospital Employee Health Division. There are three formats of the program that differ in their total length (4, 8, and 12 hours).

Progress — Current plans call for the establishment of a computer-based low back pain registry. Intake information and follow-up data will be collected on 1,000 patients with low back pain; their physical, psychological, and socioeconomic characteristics studied; and their response to treatment analyzed in a consistent fashion at 3-, 6-, and 12-month intervals.

The training function of the RRTC continues. Educational programs about low back pain for the benefit of health care professionals are being developed. These will include CME-type multispecialty programs of 1 and one-half to 2 days duration of presentation to large audiences and similar programs for use with small groups.

Inversion Therapy for Low Back Pain in Elderly Patients

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Sponsor: Department of Veterans' Affairs

Progress — A device was constructed to allow for variable angles of head down tilt. On this device, the patient is fixed by the pelvis instead of the ankles. The head down tilt is produced by flexing the knees. The advantages of pelvic versus ankle fixation are:

1) The possibility of doing abdominal exercises with the lower limbs free;

2) Straightening of the lumbar vertebral column, which increases the direct traction force for any given inclination-inversion; and

3) Increased safety of handling. The device tilts back to the "head up" position by stretching the knees. No undue physical effort or complicated maneuver is needed to reverse the inversion.

Hydraulic knee joints evaluation is conducted in order to establish firm prescription criteria for the various models of this device that are commercially available.

Biobehavioral Studies of Chronic Low Back Pain

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The project objectives are to develop and test new behavioral and physical therapy treatments for chronic low back pain (CLBP), develop a comprehensive assessment methodology, and test theories regarding the psychophysiological nature of the pain experience.

Progress — A treatment outcome study was completed testing behavioral and physical components of CLBP treatments. Groups received either standard physical therapy, a behaviorally enhanced physical therapy, or a control procedure. Currently being completed is an evaluation of traditional physical therapy methods versus learning theory methods for teaching back protection behaviors. Studies have been completed that evaluated patients' responses to mildly painful heat stimuli using a signal detection model. Other studies have examined the patterning of muscle detection model. Other studies have examined the patterning of muscle activity during various static postures and movement. Similar studies are in progress in a continuing pursuit of understanding the variables that maintain and exacerbate CLBP.

Outcome research uses behavioral and physical therapy treatments based upon the latest developments and theories in the field. The psychophysiological studies record bilateral electromyograms from major muscle groups controlling the trunk, galvanic skin response, electrocardiograms, and digital plethysmograms with a Grass polygraph, while scoring of data and laboratory control is accomplished with a PDP 11 computer system.

Preliminary Results — Both behavioral and physical therapies are uniquely effective for controlling low back pain, but neither is a sufficient treatment. Preliminary analyses indicate that an enhanced learning theory approach is superior to traditional methods for teaching back protection behaviors. Psychophysiological studies reveal that patients are more stressed than controls when making movements but that back muscle functioning is similar.

Myoelectric Analysis of Human Spine Function

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Sponsor: National Institute for Handicapped Research

Purpose — The goal of this project is to develop objective quantitative measures of lumbar muscle (erector spinae) function for patients with low back pain and measurement techniques that can be easily used in the clinic. Techniques have been developed for analysis of the frequency power spectra of myoelectric signals obtained during exercise.

Progress — Myoelectric data from 40 normal, healthy young adults performing isometric extension exercises on a back testing device at load levels of 20 percent, 50 percent, and 100 percent of their maximum voluntary contraction (MVC) force has been collected to form a normal database. A group of 36 patients with low

back injuries have been tested repeatedly during rehabilitation therapy. A linear decay frequency slope measure (mean power frequency over time, with linear slope estimate expressed as percent decrease per minute and normalized for initial frequency) was shown to correlate with load level. Significant improvement of the correlation between the linear decay fatigue measure and the load level has been obtained by expressing the load as a percent of body weight, as opposed to the traditionally used expression of load in terms of percent MVC. Additional improvement was obtained by using the mean force output over the trial to compute the percent body weight measure.

Using the normal database, a strong correlation ($r = 0.87$) was observed between the linear decay measure and load levels ranging from 20 to 120 percent of body weight, where increased load corresponded to an increased muscle fatigue rate. This curve defining normal erector spinae fatigue rates in isometric extension exercise was used to compare the measured fatigue rates of low back pain patients with expected normal values for the measured load level during exercise. Results suggest an increased fatigue rate associated with low back pain.

The Vermont Rehabilitation Engineering Center for the Study of Low Back Pain

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Sponsor: National Institute for Handicapped Research

Purpose — The Vermont Rehabilitation Engineering Center for the study of Low Back Pain was established in 1983 by a grant from the National Institute for Handicapped Research to the Department of Orthopaedics and Rehabilitation at the University of Vermont, Burlington, Vermont. The mission of the Rehabilitation Engineering Center (REC) is improvement of the diagnosis and successful rehabilitation of low back pain (LBP) sufferers.

Progress — Five long-term projects as well as a group of pilot studies are currently underway at the REC. Brief descriptions follow.

Project One: Prediction of Disability and Assessment of Rehabilitation in Low Back Pain. Project One aims to develop a reliable information-gathering system, which will broaden our understanding of both organic and functional correlates of LBP. This information will be used to develop a multi-attribute, utility model for predicting LBP impairment and LBP-related disability. The group also is involved in measuring costs associated with LBP and seeks to determine the cost-benefit ratio for various rehabilitation techniques.

Project Two: Mechanical Rehabilitation of Back Pain: Optimization of Spinal Orthoses through Biomechanical Analysis. Research is designed to develop and refine measuring techniques in order to describe the functioning of spinal orthoses in biomechanical terms. These techniques can then be used to characterize currently-available types of spinal orthoses, allowing correlation between biomechanical characteristics and effectiveness in pain reduction. Such analyses should also lead to the design and fabrication of new spinal orthoses which combine

mechanical support and electrical stimulation. Recently, this group has explored the use of ultrasound scans, valuable because they are both noninvasive and nondeleterious, to measure muscle dimensions with good results.

Project Three: Electrical Rehabilitation of Back Pain: Evaluation and Design of TEMS, TENS, and Biofeedback. If electrical stimulation is to be used as a treatment, it should be designed with the aim of modifying physical characteristics, rather than merely to reduce pain. Research is currently underway to address three questions related to this issue:

1) Can electromyography be used during a strength test to quantify the efficiency or other aspects of healthy trunk muscles?
2) Can muscular changes be demonstrated in patients with low back pain?
3) Can muscular changes be demonstrated during treatment designed to improve trunk muscle strength?

The group has carried out extensive research to determine the usefulness of electromyography as an index of muscle efficiency and to identify sources of variability in the relationship between force and EMG. Also underway is a training study designed to determine whether abdominal muscle strengthening (through exercise) produces change in EMG.

Project Four: Optimum Seating in Static and Vibration Environments. The objective of this research is to improve the seats and other spinal supports in both static and vibration environments. One of the principal means of attaining this objective lies in determining the relative contribution of each of the spinal support structures and how the overall response varies as a function of seating components and posture under static or vibration exposure. Currently, the group is investigating the effects of three sets of variables in static and vibration seating environments: 1) subjective assessments of discomfort; 2) objective changes in EMG center frequency characteristics; and 3) mechanical transmissibility factors.

Project Five: Five Pilot Studies:

A. *Digital Image Processing Techniques of Flexion-Extension Radiographs.* The purpose of the project is to produce a device which will assist clinicians in "extracting" information from flexion and extension X-rays of the lumbar spine. The use of video technology and computers promises a substantial improvement over current techniques for analyzing radiographs.

B. *Thermography: A Blinded Study of Its Efficacy in the Diagnosis of Low Back Dysfunction.* This study represents the first scientifically controlled evaluation in a clinically established and radiographically verified population of low back sufferers with herniated nucleus pulposus compared to a control group of non-affected subjects.

C. *Lateral Bending of the Lumbar Spine with Disc Herniation.* It is hypothesized that herniated nucleus pulposus at a given level of the lumbar spine is associated with asymmetry of lateral bending at that level, since patients tend to avoid a painful range of motion. Biplanar radiography is being used to document and measure the motion.

D. *Isthmic Spondylolisthesis: Instability at the L4-5 Level.* The study aims to define the clinical presentation and radiographic manifestations of this condition through an international collaborative effort.

E. *An Internal Fixator for Improved Surgical Management of LBP-Producing Spinal Instability.* The study includes the design, development, and testing of a fundamentally new spinal implant, the Vermont Spinal Fixator, which will correct the shortcomings of currently available stabilization devices and improve care of surgically treatable low back pain patients, particularly those whose spines are unstable.

Project Six: Rehabilitation Engineering for Vocational Rehabilitation of Low Back Pain. Project Six seeks to increase the rate of successful return to work for low back pain sufferers through the application of modern techniques of functional assessment and rehabilitation engineering.

Objective Evaluation of Muscle Fatigue in the Trunk

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Sponsor: Liberty Mutual Insurance Company

Purpose — As many as 75 million Americans now suffer from severe lower back pain, and each year 7 million more people develop this problem. Despite the many millions of dollars spent on innumerable treatments for the back, the majority of patients have chronic remitting symptoms. Improved methods for assessing back disorders could help to diminish the problem and the financial burden of this disabling condition.

Progress — We have begun to develop and implement a technique to provide the clinician with an objective index to measure treatment outcome for lower back musculature. This technique estimates the fatigue rate of contracting muscles by measuring the shift occurring in the frequency spectrum of the surface detected electromyogram (EMG). The dynamic interaction of synergistic back muscles during fatiguing contractions can be represented by fatigue patterns created by the different frequency shifts occurring for different muscles. Differences in these patterns associated with lower back disorders may represent functional disturbances in back muscles.

In preparation for implementing this technique, we have designed and constructed a restraining device to reliably stabilize the trunk in selective positions from sitting to standing. The device is equipped with strain-gauge load cells to monitor flexion, extension, or rotation torques of the trunk. A force meter is placed in front of the subject to provide visual feedback. In addition, preliminary modifications have been made to another device that will analyze multiple channels of EMG to track the median frequency of the signal. Plans are underway to test subjects with recurrent low back pain and normal controls.

XII. Muscular Dystrophy

A Study of the Mechanism of Spinal Collapse in Duchenne Muscular Dystrophy

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Sponsor: Regency Park Centre for Young Disabled

Purpose — Increasing spinal deformity is a distressing feature of Duchenne muscular dystrophy. The orthotic nonsurgical management of paralytic spinal deformity has been written about extensively, with conflicting results concerning effectiveness. Our own work has indicated that external supports are not effective in keeping the spine straight and that lumbar pads are not effective in supporting the spine against lateral curvature. Still lacking is a mathematical model of the spine which would lead to a greater depth of understanding of the results we see in terms of the geometry and forces involved. Our goal is to develop a mathematical model, or models, of the spine and its muscles to answer these questions:

1) Can orthotic supports apply sufficiently high forces to straighten the spine without exceeding pad-to-skin pressures which the boys can tolerate?

2) Does a hyperextended lumbar spine, combined with rigid contracture of the paraspinal muscles, result in increased resistance to lateral bending? If so, what degree of hyperextension is required? Is this tolerable to the boys?

3) Is it true that supporting oneself on the nondominant arm creates a spinal curve with convexity towards the dominant hand?

4) What factors determine whether the curve is C-shaped or S-shaped?

5) Is a flat seat or a sling seat better? (Flat seats are often said to be better, but it may be that a sling seat allows the pelvis to tilt so that the head may be brought into line over the pelvis, and this may be preferable.)

6) In what way is lateral curvature related to rotation about the long axis of the spine? Is this related to the line of pull of muscles?

7) Why do the boys lean forward in their wheelchairs? Is this related to balancing the head on the spine by placing the neck in extension to relieve the neck extensors?

8) Is it possible to recommend any strategies for posture support in special seating as a result of this study.

Progress — *Preliminary phase:* Conduct a literature search to locate the models which may be most applicable to this study. Construct a simple model consisting of a slender beam and rigid support wires as a first model.

Experimental phase: Construct an accurate model appropriate to this study which represents the head, vertebrae, and spinal muscles.

Concluding phase: Publish the results of this study in a professional scientific journal. It is important that the results of this study are sufficiently convincing to influence the thinking of medical and allied health professionals regarding the treatment of paralytic scoliosis.

A mathematical model of the paralytic spine could lead to a greater understanding of the spinal collapse so often seen in Duchenne muscular

dystrophy. It would provide a theoretical underpinning to the spinal bracing and posture supporting seating provided at Regency Park Centre. This study should provide useful further information for medical and allied health professional who treat these children.

Emotional Disorder Associated with Duchenne Muscular Dystrophy

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Sponsor: Central Remedial Clinic and Child Guidance Clinic, Mater Hospital

Purpose — The hypothesis of this study is that boys with Duchenne Muscular Dystrophy suffer from more depression and anxiety than a normal control group.

Progress — Twenty-three boys (4 to 17 years) were studied. Five of the boys who were mentally handicapped or of dull normal intelligence were excluded, leaving 18 boys in the study. These boys were matched for age, I.Q., and social class with a control group of boys without physical handicap attending normal schools. All boys and their parents were interviewed using the Rutter and Graham standardized psychiatric interviews for detection of psychiatric disorder in children. Psychological assessment of I.Q. was carried out, and teachers completed a Rutter B scale for each boy.

The prevalence of psychiatric disorder was significantly higher in the Muscular Dystrophy group than in the controls. Eight of the Muscular Dystrophy boys (44 percent) were diagnosed as having an emotional disorder of the mixed type with poor peer relationships, solitariness, anxiety, and depression as the main features. Older boys were at greater risk of psychistric disorder than younger boys. Two of the controls (10 percent) were diagnosed as having an emotional disorder with anxiety. The study attempted to make a more precise diagnosis of affective disorder using DSM-III criteria, but as all the study boys had sleep problems, poor energy, and motor retardation as part of their Muscular Dystrophy this was felt not to be appropriate. Only two of the 18 boys had ever questioned their parents about their condition, and most parents felt unable to discuss the condition with their boys. Nevertheless, many families seemed to cope remarkably well with the condition using silence as part of their coping style.

Future Plans — Further investigation of this hypothesis will be conducted and the study will be extended to include a control group with a comparable physical handicap which is non-fatal (e.g. spina bifida).

An Arm-Lifting Device

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Sponsor: The Northern Ireland Prosthetics, Orthotics, and Aids Service

Progress — In response to the needs of children with Muscular Dystrophy, a device has been made that permits the arms to be elevated. It is a simple gantry attached to a wheelchair, that suspends the arms on plastic arm-rests. Normally, counterweights compensate for the weight of the limb, allowing the residual muscle power to move the arm. There is a motorized version, powered by the batteries of the wheelchair, which is actuated by microswitches on the forearm supports.

XIII. Sensory Aids

A. Blindness and Low Vision

1. General

The Use of the Electroretinalgram to Predict Retinal Cell Activity

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The electroretinalgram (ERG) is a graphic recording of electrical potential which is measurable on the cornea and is linked, in a not so well known manner, to retinal cell activity. The retinal cells thought to cause the ERG (predominantly Mullers and receptors) act as localized current dipoles. Although the orientation and position of these current dipoles are not known *a priori*, field theory dictates that an exact knowledge of these sources would be sufficient to predict the ERG signature—given knowledge of the medium's conductivity.

The hypothesis is that the process can be worked backwards; given the potential information across the cornea one can infer from its inverse what the retinal cells taken as a localized composite are doing. Such knowledge would of course realize a quantitative retinal diagnostic.

Progress — The methodology to date has been to establish a base of data correlating retinal current dipole sources to measurable corneal potentials. Data are collected by injecting a needle dipole current source through the retinal wall of a cow eye and measuring the potential with point electrodes. The current is injected at a frequency ranging from 100 Hz to 1000 Hz. The received signal is examined with a sensitive frequency analyzer which eliminates any spurious signal sources. (The eye is a rather good antenna). Placement of both the source and the receiving electrodes is varied to ascertain the effect of: 1) tangential versus normal sources; 2) cross-corneal potentials in the horizontal and vertical planes; and 3) magnitude of signals expected with respect to both ambient noise and input signals.

Preliminary Results — Literature studies reveal the common notion that the vitreous is thought to be isopotential. Of course this cannot be (from a field theory perspective) nor is it what our test results to date reveal (although we have not made the tests *in situ*). The cross-corneal potential is, however, quite small for symmetrical source excitation (equal light stimulae over the retinal region). Off-center excitation indicates a marked increase in measurable cross-corneal potential.

Future Plans — A concentrated effort is being given to realizing a numerical algorithm to predict the corneal potential as a function of space and source

excitation. The conductivities of the R membrane, lens, vitreous/aqueous, and extraocular region are used to construct a resistive grid which is solved according to Kirchoff's voltage laws (equivalent to a finite-difference for grid solving Laplace's equation). After validating the code, we will have a convenient means of predicting corneal potential for asymmetrical retinal wall source excitations.

Intraocular Lens Implantation During and After Cataract Extraction

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Purpose — The objective of this project is to evaluate intraocular lens implantation as a means of visual rehabilitation for cataract patients. This includes implantation of intraocular lenses both during the time of surgery and as a secondary procedure. Parameters to be evaluated will include:

1) Method of cataract extraction;
2) Type of intraocular lens;
3) Position of intraocular lens;
4) Complications from intraocular lens implantation surgery; and
5) Medications to be used prior to and after the intraocular lens implantation surgery.

The research plan is to use an intraocular lens as the means of visual rehabilitation in selected patients who consent to the surgery and technique. The parameters described will be identified and the patient will be followed one day, one week, three weeks, and eight weeks after the surgery. After that time they will be seen once a year.

Methodology for the project includes selecting patients either with cataracts or who have had cataract surgery in the past and have elected to have intraocular lens implant, using age and other criteria presently accepted by the FDA. Patients are taken to the operating room after proper measurements have been taken preoperatively. Under local or general anesthesia an intraocular lens implantation, after cataract extraction, is performed. Patients are sutured according to the skill and discretion of the resident and attending surgeons.

Preliminary Results — To date, findings of the project have been as follows:

1) Intraocular lens implantation in the selected patient population has been a viable, safe alternative for visual rehabilitation after cataract surgery. In fact, in most cases intraocular lens implantation is the preferred method of visual rehabilitation after cataract surgery.

2) The exact surgical technique chosen appears to depend more upon the competence and familiarity of the surgeon rather than agreement upon any one particular exact technique. In general, it appears that a posterior chamber intraocular lens implant with an extracapsular procedure is the preferred technique for use with the patient who is having a cataract extraction and lens implant in one procedure. The postoperative complications in the long run appear to be diminished with this technique.

In patients undergoing secondary intraocular lens implantation, an anterior chamber lens appears to be the preferred technique.

Implementing Micro-Technology and Computer-Assisted Learning

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Sponsor: Research Centre for the Education of the Visually Handicapped

Purpose — A series of mimeographed newsletters have been produced at the Research Centre, describing progress on producing and evaluating software for the use of blind adults and children. Copies of the newsletters and further details of the various projects can be obtained from the first-named investigator at the Research Centre.

Assessing the Manual Dexterity of the Blind

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Sponsor: Research Centre for the Education of the Visually Handicapped

Purpose — The Purdue Pegboard Test of Manual Dexterity has been administered to nearly 1,000 newly-blinded people in the course of their rehabilitation, and the investigators expect to publish an account of their findings within the next few months. Further details can be obtained from the first author.

Blind in Birmingham—A Pilot Survey of Knowledge of Available Services

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Sponsor: Research Centre for the Education of the Visually Handicapped.

Purpose — This paper gives the results of a survey designed to obtain from blind people information about their personal and vocational status, their self-perceived needs, and their knowledge of the services available to them within England's second-largest city, Birmingham. The names of 50 people were drawn at random from the city's register of blind persons, and they were interviewed, face-to-face, by the writers.

The resulting report was published in the New Beacon, March 1984, Vol. 68, No. 803.

Survey of Local Authority Social Rehabilitation Services for Visually Handicapped Adults

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Sponsor: Royal National Institute for the Blind

Purpose — Phase One is a survey of a sample of local authorities in England and Wales, in order to examine the following:

1) Current levels and methods of provision of social rehabilitation services for visually handicapped adults;

2) The aims and attitudes which inform the policy of local authorities in the provision of social rehabilitation for the visually handicapped; and

3) How local authorities perceive the present and future role of the RNIB in the provision of social rehabilitation on a national scale.

The survey was conducted by postal questionnaire and personal interview among a proportionately stratified sample of 19 local authorities in England and Wales.

Phase Two is a survey of a sample of visually handicapped adults. This survey aimed to assess the clients' expectations as well as their evaluation of current rehabilitaton procedures, in order to determine what kind of rehabilitation services visually handicapped themselves require. The survey was administered by personal interview among a sample of 153 recently registered blind adults, stratified by age.

Preliminary Results — A publication has been issued with the following title: Local Authority Social Rehabilitation Services to Visually Handicapped People, RNIB, April 1985.

Project Poly-Son: A Computer Sound Peripheral Device for Visually Handicapped Children and Adolescents

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Sponsor: National Institute for Health and Medical Research, and National Agency for Research Valorization

Purpose — A device has been developed, that will be usable by blind and partially sighted children and adolescents, to allow them an active practice of Computer Science. It consists of a sound peripheral which permits the creation and the operating of sound objects—music, words, sound-effects—through programs written in a microcomputer in high-level languages. For very young children (4 to 7 years old) simplified commands use a perforated-card reader.

This device offers a series of immediate applications in several domains; 1) initiation to technology and Computer Science; 2) logical and mathematical games; 3) sound information games; and 4) training for programming.

Easily usable by sighted subjects, this device makes it possible to organize common activities between sighted and blind individuals and is likely to facilitate the integration of the latter in schools, universities, and professional institutions.

Early commercialization for the sound peripheral is predicted by Dr. G.C. Lairy, Research Director of the Group for Research in Theory and Practice in Psychopathology of Infants, which is a division of the National Institute for Health and Medical Research (INSERM).

Rabbit EERG Response to White-Noise-Modulated Stimuli

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — If severe hemorrhaging occurs in the human eye, the media can become so opaque that light from normal illumination is unable to penetrate the curtain of blood. It is important in this situation to determine whether the retina has normal photopic and scotopic responses. A yes/no answer is usually adequate, but the scotopic measurement is rarely accurate and the photopic protocol is usually impossible.

We propose a totally new approach to characterizing the ERG for the above paradigm, i.e., a gaussian white-noise modulation of current will be presented as the stimulus, and the Electrical ERG (EERG) response will be measured. In most practical applications of the white-noise protocol, the small (gaussian) amplitude distribution of the stimulus is a very undesirable feature. On the other hand, the white-noise characterization scheme is highly resistant to uncorrelated noise; also,

nonlinear characteristics (e.g. refractory periods) often can be resolved. Hence, it seems to be an ideal protocol for the EERG.

In an attempt to identify the functional significance of the white-noise EERG, a two-input experiment will be attempted: while the electrical stimulus is presented, a light stimulus will be superimposed. Both stimuli will be white-noise modulated and a "cross-kernel" will be calculated which will reveal how an impulse of light interferes with an impulse of current. For example, if the bipolar cells are responding to a light impulse, then they will respond differently to a superimposed current stimulus. Conversely, the current initiated response can interfere with the light response. Hence, it will be possible to identify the corresponding components of each ERG response based on the latencies indicated by the cross-kernel.

Progress — During the first two months of this project, we have written computer programs to acquire and analyze the anticipated data. We also have begun assembling electronics which will generate the electrical stimulus and amplify the EERG response.

Princeton Cutaneous Research Project

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Sponsor: National Institutes of Health

Progress — The reporting period has been made in the following projects:

P-26 Intermodal Perturbations of Temporal Order Judgments;

P-32 Computer Generation of Vibrotactile Patterns;

P-47 Vibrotactile Pattern Recognition, Discrimination, and Masking; and

P-49 Vibrotactile Supplementation of Lipreading Information.

The following is an account of progress made on Project P-32 as part of the Princeton Cutaneous Research Project's Report No. 45, June 1985.

During the last report period, two major modifications to the existing laboratory hardware have been made. First, there was completed a Senior Independent Project that enables us to control the Optacon, a reading machine for the blind, with a Commodore-64 computer. The second change involved the purchase of an IBM-XT computer to replace the aging DEC PDP-8/f computer in its role as controller of the large vibrotactile matrix. At the same time, an interface system is being developed to provide for control of the Optacon array by the IBM-XT. Details of these changes are given below:

The first project was completed at Princeton. The complete thesis will be available on request to interested readers. In brief, the interface connects the User Port of the CBM-64 to the Input/Output connector of the Optacon. No modification of the Optacon is required other than disabling the onboard clocks and inhibiting the camera input by grounding the appropriate pins on the I/O connector. Patterns to be generated by the Optacon are downloaded from disk storage into the computer's memory as blocks of 24 8-bit digital words. The rightmost 6 bits of each word are used to define the on-off status of each pin in one of the Optacon's 24 rows of vibrators. Each word is placed onto the parallel output port seriatim as the system clock, built into the interface, counts off 24 time

intervals within each frame period. Level-shifting circuitry within the interface converts the 5-volt computer-generated pulses into the requisite −7.5 volt and −18.25 volt pulses for the Optacon. These voltage levels are provided by the Optacon, so the interface requires no separate power supply. Frame loading is conducted under 6510 microprocessor machine-language instruction, while user input and output is handled by the master program, currently written in the BASIC language. Improvements in the software are being made to allow the system to have the versatility of the original matrix system.

The second project involves developments of an IBM-XT-based system for control of both the original vibrotactile matrix system and the Optacon. At this time, data are being downloaded from the DEC PDP-8/f into the IBM-XT for analysis, using a direct connection ("null modem") and a simple Terminal Program. The Optacon interface (under construction) will be based primarily on the system developed in the laboratories of the University of California, Santa Barbara, while the Vibrotactile Matrix interface will involve a simple parallel output bus. We also have incorporated ideas from the IBM-Optacon interface system developed at the University of Wisconsin. With these changes, we expect to be able to conduct experiments with a more reliable system, as well as to be able to examine inter-site interactions in the perception of vibrotactile patterns. Furthermore, the exceptional software base that exists for the IBM-XT will allow for improved data analysis.

Aids for the Deaf-Blind

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Sponsor: National Institute of Handicapped Research and the Smith-Kettlewell Eye Research Foundation

Purpose — A major new area of research for our Center in the field of aids for the deaf-blind is the investigation of robotics applications for this target population. We have undertaken a project to design a simplified state-of-the-art robotic finger-spelling system. Through the courtesy of Dr. Sam MacFarland of the Southwest Research Institute REC, we obtained on loan an early prototype of such a robotic finger-spelling system, and through collaborative arrangements with Stanford University and the Veteran's Administration, we studied the feasibility of new approaches to this problem. We contracted with Stanford University students, supervised by Dr. David Boonzaier (a visiting staff member at Smith-Kettlewell and Stanford) to construct an experimental prototype robotic finger-spelling system which could be used for our investigations.

The prototype has been completed. It is designed in such a way that each finger joint can be "frozen," allowing us to study the minimum required number of degrees of freedom for a future device.

We have also engaged the services of Dr. Harry Bornstein (formerly of Gallaudet College) to conduct a theoretical analysis of the finger-spelling system used by the deaf-blind, in order to suggest possible simplifications (especially those which involve reductions in the number of required fingers or joints). Initial results indicate that a greatly simplified version can be produced, and modern robotics technology should enable further reductions in cost. Should this project

be successful, the capability for both face-to-face and remote communication for large numbers of deaf-blind individuals (especially those unfamiliar with braille) will be greatly enhanced.

Progress — Several exciting new developments have occurred in this area during the past year. The Telebraille (a telephone communications system for the deaf-blind) is now being manufactured by TSI. We are particularly interested in this development because the early prototypes of the Telebraille were developed under a collaborative arrangement between the Smith-Kettlewell REC and TSI.

During this reporting period, we also have developed an inexpensive new vibratory paging system for the deaf and deaf-blind. It is currently being tested by the Kansas Parents Association for Hearing Impaired Children.

Microprocessor-Based Job Instrumentation

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Purpose — This center has completed two microprocessor-based job instrumentation projects. The first of these was a Talking Telephone Switchboard Monitor, which has been successfully tested in service by a blind operator using a 30-line switchboard. During the coming year, this design will be adapted to make it more suitable for replication by others. The second project is a microprocessor-based voice read-out system for monitoring the status of refrigeration pressure gauges. This design is about to be field-tested by a blind refrigeration engineer.

Progress — The results of these projects will be applied toward the design of a "universal" microprocessor-based job instrumentation system, capable of accepting inputs from a wide variety of instruments and transducers commonly used in vocational situations. Several output options also will be available, including speech and auditory-braille coding. Our experience with the two initial projects described here has enabled us to conceive a "universal" approach which can be readily adapted to different job situations by merely inserting an appropriate Eprom. We believe this new approach will enable both an increase in employment of the blind in varied fields, and a decrease in the cost of the specialized instrumentation which has hitherto been needed.

Form Board

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Sponsor: National Institute of Handicapped Research and the Smith-Kettlewell Eye Research Foundation

Progress — During the past year, we have developed a new version of our electronic Form Board. This device provides both auditory and tactile feedback for blind and multihandicapped children as they match shapes and figures on the top of the Form Board. The new version of this device utilizes magnetic read switches, rather than mechanical switches, to initiate the auditory and tactile feedback, obviating the problem of accidental closure of the switches through finger contact. The design has also been repackaged in a cosmetic plastic case suitable for production. This project is now complete, and a manufacturer is being sought with the assistance of the Electronic Industries Foundation REC.

New Volatile Braille Display

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Sponsor: National Institute of Handicapped Research and the Smith-Kettlewell Eye Research Foundation

Purpose — We have conceived a new approach to the development and production of single-line volatile braille displays for use by the blind in accessing computer information. Our new approach, using inexpensive parts of high reliability, should enable us to overcome the problems of cost and reliability associated with earlier displays. We have fabricated a single-cell prototype to test the feasibility of the system, and work is currently proceeding on the first 20-cell version for evaluation.

New Ways to Access Microprocessor- and Computer-Based Aids

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Sponsor: National Institute of Handicapped Research and the Smith-Kettlewell Eye Research Foundation

Progress — During the past year, we have conceived and implemented new approaches to computer-based learning systems for blind children. The connection of physical objects and systems (such as manipulata, clocks, puzzles, word games, etc.) to the computer, bypassing the conventional keyboard, both improves the motivation of the student and increases the flexibility and learning value of the computer-based sensory aid. We have tested this concept by constructing a system for teaching blind children to tell the time, using a large clock (with movable hands) connected as a peripheral to an Apple computer. Other peripheral modules serving a wide variety of functions can be added.

Several well-known commercial manufacturers involved in the computer industry have expressed interest in the future potential of these computer-based learning modules.

Geriatric Research

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Sponsor: National Institute of Handicapped Research and the Smith-Kettlewell Eye Research Foundation

Purpose — Under private funding, we have conducted research to determine the contribution of the vestibular system to the problems of balance and mobility faced by the aging population, both sighted and blind.

Progress — Vestibulo-ocular reflexes (VOR) in the blind were found to have characteristic abnormalities caused by the loss of vision (see previous Annual Report). We have implemented a mathematical model of the VOR on a microcomputer. That model, which is based on the actual neuroanatomy of the system, accurately simulates normative vestibulo-ocular responses. We are currently simulating the responses of the blind to determine the anatomical structure adversely affected by the loss of vision.

Vestibulo-ocular reflexes of older individuals will be measured to assess the effects of aging on the VOR. The procedures and techniques used to assess the VOR in the blind will be used to assess the VOR in the aged. Our findings will indicate whether visual-vestibular interactions contribute to the balance difficulties experienced by the aged.

Oculo-Encephalographic Communication System

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Sponsor: National Institute of Handicapped Research and the Smith-Kettlewell Eye Research Foundation

Progress — The new method of communication by eye gaze, developed by Erich Sutter, Ph.D., has reached a new phase in its progress towards the attainment of a truly portable system. The system has now been implemented using a Motorola 68000 processor, and is now transportable in the sense that a connection to a mainframe computer is no longer necessary. Simultaneously, substantial improvements in the signal processing have been made in order to make the system's operation faster and more efficient.

The fabrication of two even more transportable prototypes will enable us to pursue our collaboration with the Trace Center REC and the Artificial Language Laboratory of Michigan State University. Those laboratories will develop and refine the communication interfaces for the system. Zygo Industries of Portland, Oregon has contracted to act as manufacturer for the completed system.

Pediatric Program

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Sponsor: National Institute of Handicapped Research and the Smith-Kettlewell Eye Research Foundation

Purpose — The innovative Pediatric Rehabilitation Engineering Program, which was established with seed funding from the Smith-Kettlewell Eye Research Foundation, focuses on the development of new vision testing and screening technology for infants. In many visual handicapping conditions, the critical phase occurs very early in life (the first few weeks and months), and detection and intervention at this stage is crucial for satisfactory rehabilitation. Major achievements of our pediatric research program to date have been the development of a rapid visual-evoked potential screening system for assessment of infant visual function, along with development of a simple photorefractive technique using inexpensive equipment.

Progress — During the last several months, we have successfully extended the sweep Visual-Evoked Potential (VEP) technique, which we developed for accuity measurement, to the determination of contrast thresholds. In collaboration with Dale Allen of the University of California, Berkeley, School of Optometry, we conducted a comparison study of the sweep VEP and conventional psychophysical measurement of the contrast sensitivity function. The two measures were very highly correlated, suggesting that the sweep VEP may be used as an objective measure of contrast sensitivity. We also have measured infant contrast sensitivities using the same method, and have found contrast sensitivities that are markedly higher than those reported using behavioral methods and older VEP techniques.

Progress has also been made in developing a computer ray-tracing model of the photographic refraction system this center has been developing over the last two and a half years. The model enables us to predict the dioptic error of each eye, based on measurements of retinal reflexes such as those obtained in retinoscopy. The significance of this recent effort is that we are now able to determine the refractive error using an analytical method that includes this important parameter, and we expect that a significant improvement in the accuracy of our photorefractions will result from using the new analytical model.

Evaluation of Computer Hardware and Software for Visually Impaired Persons

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Sponsor: National Institute of Handicapped Research and the Smith-Kettlewell Eye Research Foundation

Purpose — The TASO System, developed by Dr. Joachim Frank of West Germany has been evaluated at this center. The system utilizes an Osborne computer with a specially adapted keyboard (containing vertical and horizontal sliding potentiometers with auditory feedback) for screen access. Initial results have been most favorable, and have enabled the center's blind engineers to become fully integrated with the word-processing system utilized by the rest of Smith-Kettlewell. Feedback from our staff has assisted Dr. Frank in updating his design, and we are currently providing assistance in selecting appropriate commercial document-reading equipment to further extend his machine's capabilities.

We also have evaluated programs for the Cranmer Modified Perkins Brailler, and given appropriate feedback to Maryland Computer Services. In particular, we evaluated a geographical graphics package, which we found required modifications. Evaluation results have been shared with the company.

Portable Electronic Braille Note-Taker

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Sponsor: National Institute of Handicapped Research and the Smith-Kettlewell Eye Research Foundation

Purpose — We have developed a new concept in braille note-taking for blind students and adults. Our goal is to provide an electronic alternative to the traditional pocket braille slate, which is both slow and noisy in use. Our proposed system will provide a quiet, rapid, and pocket-size replacement for this traditional note-taking medium. Initial development work on this project is under way, and full details will be available at the end of the 1985-86 reporting period.

Sensory Substitution

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Sponsor: VA Research and Development Service

Purpose — Following the loss of vision, rehabilitation engineering approaches have been shown to be effective in providing substitute sensory information. An example of this is the ability of the congenitally blind person to perceive visual information picked up by a TV camera and provided in a tactile form onto his back. Further exploration of this concept of sensory substitution is being done with expansion to other disabilities. Specific areas that are being explored are:

1) the provision of pressure shear and proprioceptive information for an insensate diabetic foot in order to reduce the incidence of ulcer formation leading to amputation, and to improve the ataxic gait;

2) the provision of "touch" and vibratory information that a blind diabetic patient receives through the use of a long cane;

3) the provision of contact sensation to minimize pressure sore formation in spinal cord injured persons;

4) the provision of contact "touch" and other superficial sensation to insensate hands.

Demonstration of a Low-Vision Aid Clinic as an Employment Enhancement Technique

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Sponsor: National Institute of Handicapped Research

Purpose — The purpose of this study is to determine whether providing a partially blind person with a low-vision aid (LVA) will enhance his or her employment, as measured by productivity and self-satisfaction in employment in sheltered settings.

Progress — In Phase I of this study, 50 partially blind persons from the Mississippi Industries for the Blind (MIB) were randomly selected to participate in this study. These subjects were serially screened for LVA prescription by 1) complete medical and extraocular examinations and 2) Goldman field examination. Following LVA prescription as required for maximum efficiency in the subjects' work environment, specific training was provided to encourage utilization of the LVA on the job.

Of the 50 participants in this study, 32 were prescribed LVAs. Analyses of payroll data and other interview data were collected at 30 days, 6 months, and 12 months after receipt of the prescription. An analysis of the data through the 6-month period shows that the LVA group has responded favorably to the aids. The LVA group questioned said that they could work better with the aids and had little or no trouble using them.

Future Plans — An interim progress report will be published. Subjects for Phase II of this study will be selected from sites other than MIB during the upcoming year.

Industrial Services Program Model for Sheltered Workshops for Legally Blind Workers

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Sponsor: National Institute of Handicapped Research

Purpose — To determine whether the Industrial Services Program Model (ISP) enhances the employability of blind persons. The research project addresses two questions:

1) Does the ISP pre-employment training increase the productivity of blind workers who are newly employed in a protected industry?

2) Does an adapted ISP increase the productivity of blind workers who are newly employed in a competitive industry?

A multiple time series design has been utilized to investigate the effectiveness of an ISP on the performance of twelve blind persons who received ISP pre-employment training. The control group consisted of the last 12 employees hired by MIB prior to the initiation of in-plant ISP training.

A non-sheltered setting in which blind persons could participate in ISP training in Mississippi was sought, but not found.

Preliminary Results — Preliminary analysis of the data collected at MIB may be interpreted as indicating no significant differences between the experimental population which received ISP training and a control group which did not. Data collection on this project has been completed.

Assessment of Current Career Development Intervention Services and the Needs of Blind and Severely Visually Impaired Individuals

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Sponsor: National Institute of Handicapped Research

Purpose — The purpose of this project is 1) to assess current career development services for blind and severely visually impaired persons and 2) to assess the career development service needs of these persons. The project addresses two questions:

1) How effectively do current career development intervention strategies facilitate the employment and career development of blind and severely visually impaired persons?

2) What are the career development needs of blind persons?

The research design determined the extent to which current career development services meet the career development needs identified by blind students, their teachers, their parents, rehabilitation agency personnel, and blind adults.

Preliminary Results — Analysis of the data collected during this project has been divided between the impressions of blind persons of their career development needs and the perceptions of educators and rehabilitation professionals of the extent to which career development needs of blind persons are being met.

Illumination Level and Color Contrast Studies

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Sponsor: National Institute of Handicapped Research

Purpose — The purpose of this project is to determine whether manipulating the illumination level, and altering the color contrasts, significantly increases the productivity and comfort of severely visually impaired production workers. Specifically, this project addresses three questions:

1) To what extent does increasing or decreasing illumination affect the performance of severely visually impaired production workers on a task performed visually?

2) To what extent does varying color contrast affect the performance of severely visually impaired production workers on a task performed visually?

3) To what extent does optimizing the illumination of the work site and the color contrast of materials used in performing tasks in the work site increase the productivity and comfort of severely visually impaired production workers?

Progress — Fourteen subjects, nine of whom utilize high-power low-vision aids prescribed in RRTC/B-LV project R-1 (Demonstration of a Low Vision Aid Clinic as an Employment Enhancement Technique), were tested with respect to various illumination levels and color contrast conditions to determine the specific levels of these variables which maximized their productivity and comfort. The job site of each subject was then modified in accordance with that subject's optimum illumination and color conditions.

The design was an A-B-A-C-A-D-A single subject withdrawal design, with A representing non-treatment phases and B, C, and D representing light-only, color-

only, and color-plus-light modification phases, respectively. Before and after each modification (or treatment) phase, the modifications were withdrawn, resulting in non-treatment phases alternating with treatment phases. The dependent measures were productivity rates and comfort ratings.

Functional Outcome for Blind or Severely Visually Impaired Clients of State Rehabilitation Agencies

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Sponsor: National Institute of Handicapped Research

Purpose — The purpose of this study is to identify the factors which may predict the results of rehabilitation services provided to blind and severely visually impaired clients of selected state rehabilitation agencies. More specifically: To what extent can the functional outcome of blind individuals closed successfully or unsuccessfully rehabilitated by state rehabilitation agencies be predicted by 1) services received, 2) client characteristics, 3) county economic conditions, and 4) proximity to rehabilitation services?

Progress — A stepwise multiple discriminate analysis was utilized to assess functional outcomes and related characteristics of 619 blind and partially blind persons whose cases were closed as either successfully or unsuccessfully rehabilitated by state rehabilitation agencies in Florida, Kansas, Mississippi, and Ohio. Subjects were selected at intervals in proportionate numbers according to rehabilitation case closures from the four state agency populations in FY 1978, 1979, and 1980. Subject totals were: Flordia, 146; Kansas, 42; Mississippi, 124; and Ohio, 307; for a 3-year grand total of 619. With the exception of Kansas, for which data for 1978 were unavailable, data are evenly distributed over 3 years.

A stepwise multiple discriminate analysis was used to develop a multiple discriminate function to predict the work status outcome criterion variable. This process allows the computation of the best possible combination of predictive variables associated with the functional outcome group. Other analyses will be conducted as are deemed appropriate.

Publication of a report of the findings of this study is planned for 1986.

Visual Field Limitation in the Patient with Dementia of the Alzheimers Type

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Sponsor: VAMC St. Cloud, (station-appropriated funds.)

Purpose — This paper investigates the existence of a visual field limitation and its effect on the advanced Alzheimers patient. The data presented was obtained by testing 12 patients with Alzheimers disease and 12 control patients. The control patients were demented from causes secondary to reasons other than Alzheimers disease.

The results indicated that patients demented due to Alzheimers have visual field losses significantly greater than other demented patients. This significant visual loss is of importance in assisting in differential diagnosis and in planning patient environments.

Development of Electromechanical Vocational Assessment Technology for Finger Dexterity and Hand/Foot Coordination

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Sponsor: National Institute of Handicapped Research

Purpose — The purpose of this study is to determine the reliability and validity of six pre-employment evaluation and training electromechanical work task units (EVAT). Specifically: Are each of the six electromechanical work task units reliable and valid pre-employment assessment technologies for blind or severely visually impaired employees?

A test-retest over time design was utilized on 30 subjects drawn from the following rehabilitation facilities and sheltered workshops: Mississippi Industries for the Blind, Jackson, Mississippi; Addie McBryde Rehabilitation Center, Jackson, Mississippi; Royal Maid Association for the Blind, Hazlehurst, Mississippi; Regional Rehabilitation Center, Tupelo, Mississippi; Royal Maid Association for the Blind, Tupelo, Mississippi; and Louisiana Association for the Blind, Shreveport, Louisiana.

Background data were collected on all subjects tested. These data included: date of birth, medical and psychological information, work history, and level of education. Additional information included relevant vocational evaluation and assessment scores: Valpar, WRAT, IQ, and the Pennsylvania Bi-Manual Dexterity Work Sample. For individuals who were employed at the time of testing, a job analysis and ratings by their supervisor were obtained.

Reliability levels indicating test accuracy over time were established by the computation of a coefficient of stability obtained through test-retest procedures. Product-moment correlation is the primary method utilized. A standard error of measurement also is being determined.

Practice efforts on the test-retest reliability have been minimized through data collection procedures. The length of interval between testing periods and the lack of intervening training activities reduces the impact of practice on the reliability measure.

Preliminary Results — A report of the findings of this study will be available during 1986.

Adaptation of the Vocational Educational Readiness Test

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Sponsor: National Institute of Handicapped Research

Purpose — The purpose of this project is to determine whether each of the Vocational Educational Readiness Tests (VERT) adapted for blind and severely visually impaired persons is an appropriate (reliable and valid) assessment tool for determining the readiness of these persons to enter training programs for auto mechanics, electrical wiring, quantity foods, and industrial sewing.

Progress — Each of the VERT modules was screened to determine the elements requiring vision. The training samples were then constructed at the field work site. Project personnel have been provided training and consultation in use of the training samples and recording of project data. Based on the training sample data

being collected at the field test site, revisions to the training samples or training sample procedures are being made.

A test-retest over time design is being utilized. The tests are being administered to present trainees and employees at two different locations: Royal Maid Association for the Blind (Tupelo, MS) and Regional Rehabilitation Center (Tupelo, MS). Participants have been randomly selected from a group of volunteers from each location. There have been 15 individuals tested and retested on each work task. Sighted standards and norms have been developed for blind persons. Baseline data have been collected for all training samples.

Reliability levels will be established by computation of coefficients of stability obtained through test-retest procedures. Retests will be conducted within a 90-day period. No additional training on the work sample will be conducted. Practice effects will potentially impact any performance-based assessment technique. The length of the interval between testing periods and no-training activities reduces the impact of practice on the coefficient of stability.

Validity will be determined in two ways. Concurrent validity will be established by correlating training task scores with the subjects' scores on other vocational evaluation systems for which similar tasks are available. Content validity will be established by comparing the job analysis of the job on which the training sample was designed with the resulting training sample.

Other data will be gathered on the client data form. This information will include visual disability and information on secondary disabilities.

Test and retest data on three of the four assessment modules have been collected. Analysis has primarily focused on the auto mechanics module. A "powder puff" class of sighted persons also was assessed with the adapted VERT auto mechanics module. All tasks save one were shown to be both reliable and valid.

Further modifications were made in the procedure to administer the auto mechanics module, and a standardized instruction manual has been written. The auto mechanics module is currently being field tested at the Arkansas Enterprises for the Blind. Additional field sites will include the Alabama Institute for the Deaf and Blind and the Criss Cole Rehabilitation Center.

Future Plans — This research design will be employed to establish the reliability and validity of the industrial sewing, auto mechanics, and quantity food modules.

Training Opportunities Profile for Visually Impaired Persons

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Sponsor: National Institute of Handicapped Research

Purpose — The intent of this project is to develop a series of assessment materials that can be used in vocational evaluation centers to assess the capabilities of blind persons to enter training in one of the five following job clusters: 1) computer programming, 2) counseling/social work, 3) management, 4) sales, and 5) allied health. The research question may be stated as: What are the characteristics which indicate the aptitude of blind and severely visually impaired persons to enter training in one of five job clusters?

Progress — Technical and professional job clusters were identified as meeting the conditions of 1) a high number of employed or in-training blind persons and 2) labor market forecasts indicating employment possibilities which will continue to exist for the foreseeable future. Information concerning the job task and manpower requirements was obtained from literature reviews and interviews with sighted and blind workers as well as with trainers of blind and sighted persons in each of the job cluster areas.

This information was utilized in constructing assessment materials for each job cluster. The assessment materials will be criterion referenced for use in career decision-making by blind persons.

The first phase of this project was a review of assessment instruments used to test the abilities of blind and severely visually impaired persons. The result of this effort was the publication in 1984 of Work Samples and Visually Impaired Persons: A State-of-the-Art Review and Resource Manual.

The second phase of this project is currently in progress. A comprehensive literature review has been completed for each of the five job clusters. Job analyses have been conducted through literature reviews and interviews. Critical occupational tasks, traits, and dimensions have been identified. Drafts of the manuals for each of the job clusters have been completed.

Future Plans — Manuals to assess the likelihood of blind persons entering jobs in each of the five job clusters will be published during 1986.

Pre-Vocational Work Ability and Success-Acquisition Training of Deaf-Blind and Other Multiply Visually Disabled Individuals

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Purpose — This project follows preliminary findings of the RRTC/BLV research project, Development of Electromechanical Vocational Assessment Technology (EVAT) for Finger Dexterity and Hand/Foot Coordination. Three of the EVAT units found to be reliable and valid assessment technologies of finger dexterity and hand/foot coordination will be adapted to determine whether they may be utilized as pre-vocational work ability and success-acquisition training technologies. The Research Questions: Which, if any, of the adapted EVAT work task units selected for inclusion in this project, when used as pre-vocational training technologies, provide deaf (or otherwise multiply disabled) blind persons with transferable pre-vocational work skills and success-acquisition skills?

A single subject research design will be employed to assess the utility of three EVAT task units with 15 deaf or otherwise multiply disabled blind children between 14 and 22 years of age in Jackson, Mississippi.

This project will be conducted in three phases. During the first phase, the EVAT task units will be modified for use by the subject population, and a pilot study with the adapted equipment will be undertaken. Training manuals also will be developed. A brief case history of each of the subjects will be collected during this phase as well.

The second phase will consist of assessment of each subject's pre-vocational skills.

During the third phase of this project, each subject will be trained in the use of the EVAT task units. On subsequent trials, the data for the following table will be collected.

Progress — Each of the EVAT units to be used in this project were modified for use with deaf-, or otherwise multiply disabled-, blind persons. Instruction manuals for using each training task unit for pre-vocational training classes were drafted.

All three units together with revised standardized instructions were pilot tested with 13 deaf-, or otherwise multiply disabled-, blind students at the Mississippi School for the Blind.

Future Plans — The reliability and validity of the adapted work task units will be investigated. A report of the findings of this study will be published.

Assessment of Eye-Hand Coordination and Manual Dexterity Under Different Illumination Levels and Contrast Conditions

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Sponsor: National Institute of Handicapped Research

Purpose — This project is an extension of the strategies and techniques developed in RRTC/BLV project R-5, Illumination Level/Color Contrast Studies, to increase knowledge about the effects of modifying the visual environment on various types of visual performance which are basic to many work abilities. The research questions are:

1) To what extent do environmental modifications such as changes in illumination level, contrast, size, and presentation speed affect performance of low-vision subjects on tasks involving perceptual and psychomotor skills?

2) How do these environmental characteristics interact to affect performance, and are the effects and interactions consistent across tasks requiring different combinations of skills?

3) How much variation exists among low-vision persons with respect to such effects, and can relationships to subject characteristics be identified?

The tasks on which dependent measures are to be obtained tap basic perceptual and psychomotor skill abilities which underlie much visual functioning. These tasks will be novel to the subject and thus require a continuous use of vision. The testing for optimal stimulus characteristics will be done on multiple tasks, each requiring a different combination of perceptual and psychomotor skills, allowing for greater generalizability to on-the-job skills and an investigation of the consistency of stimulus effects across a variety of tasks.

The number and type of independent variables or stimulus characteristics have been increased over those used in the previous project, resulting in the following improvements:

1) Contrast will be studied in terms of its components, luminance contrast, and chromatic contrast.

2) For each task employed, the two primary independent variables to be manipulated are illumination and luminance contrast. In addition, each will include one or more of the following task characteristics as independent variables: illumination, size, speed of presentation, and chromatic contrast.

Data collection on each subject will be completed in a single day, rather than the months required in R-5. This allows for better control of motivational variables and the elimination of history effects.

The subjects to be included in this study will be 40 persons who are legally blind in the State of Mississippi. They will be obtained through the cooperation of Mississippi Vocational Rehabilitation for the Blind. Selecting subjects in this manner should better insure their representativeness.

Instrumentation, tasks, and independent variables to be used in the project have been designed to answer the research questions.

Progress — Construction of stimulus sets, modifications of apparatus, and refinement of testing procedures were completed. The entire procedure was pilot-tested on 50 subjects with simulated visual acuity losses. This was done not only to test the methodology and procedure, but also to provide data for a "standard measure" to which the performance of actual low-vision subjects might be compared. These data have been analyzed to determine the relative strengths of variable effects, presence of interactions between variables, etc.

Testing of rehabilitation clients has begun. In addition to data collection for research purposes, each client's performance on each task under the various conditions is examined in relation to his or her career goals. An evaluation report is submitted to the client's rehabilitation counselor, providing feedback on the client's performance, information concerning the relative importance of environmental variables to his/her performance, and recommendations for career advancement.

Future Plans — Analysis of the data collected will be completed. A report of the findings of this study will be published.

Selected Career Development Factors and Outcome of Vocational Rehabilitation Services Provided Middle-Aged and Older Blind Persons

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Sponsor: National Institute of Handicapped Research

Purpose — This study is an intensive investigation of one of the sub-populations identified in RRTC/BLV project R-4, Functional Outcome for Blind/Severely Visually Impaired Clients of State Rehabilitation Agencies. The research questions are:

1) In agencies providing services to them, do middle-aged and older blind clients of rehabilitation agencies differ from younger clients, as well as from one another, with respect to (i) disabilities (primary, secondary, tertiary), (ii) proximity to their rehabilitation counselor or to a rehabilitation facility, (iii) services received, (iv) funds expended, (v) vocational skill levels, and (vi) functional outcome? If yes, to what extent with respect to each?

2) Do the functional outcomes of blind middle-aged and older persons closed either successfully rehabilitated or unsuccessfully rehabilitated by state rehabilitation agencies differ from each other with respect to (i) services provided, (ii) client characteristics, and (iii) county economic conditions? If so, what factors predict successful as opposed to unsuccessful closures?

A multivariate discriminate analysis will be utilized to assess the functional outcomes and related characteristics of middle-aged and older persons from the data base of 619 blind persons whose cases were closed either as successfully (status 26) or unsuccessfully (status 28) rehabilitated by state rehabilitation agencies in FY 1978, 1979, and 1980 in Flordia, Kansas, Mississippi, and Ohio. Middle-aged subjects will be defined as those persons who were 40 to 54 years old at referral. Older subjects will be defined as those persons who were 55 years of age or older at referral. Younger subjects will be defined as those persons who were 39 years of age or younger at referral.

Progress — Subjects were selected at intervals according to rehabilitation totals from the four state agency populations in FY 1978, 1979, and 1980. The data base has been built from individual case files abstracted for project R-4. The same statistical analytic procedure will be employed in this project as has been utilized in R-4.

A review of the literature and an analysis of selected demographic characteristics of the three-sub-populations have been completed.

Future Plans — Analysis of data on this project will be completed in 1986 year. A technical report of findings will be available from the Rehabilitation Research and Training Center on Blindness and Low Vision.

Sensory Aid Technology: A Career Development Intervention Strategy for Blind and Severely Visually Impaired Persons

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Sponsor: National Institute of Handicapped Research

Purpose — The purpose of this study is to determine the effects of sensory aids on the employability and career development of blind and severely visually impaired persons.

The instrument to be developed was constructed by the RRTC/BLV staff with consultation from a sensory aid technology specialist, and a data formatting specialist. The data formatting specialist was used to assure efficiency in data entry and analysis. The survey instrument was pilot-tested in Mississippi. The sensory aid technology specialist and data entry specialist were asked to review the responses. Changes were made as warranted. The responses to the survey were analyzed using SPSS-X 83 release. Probable programs to be used include crosstabs, report, etc.

Predicting the Visual Abilities of Partially Sighted Persons

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — More than three-fourths of America's legally blind population may have useful, residual vision. Many of these people could benefit from visual aids, but either they have not had them prescribed or they are not using the aids they have been given. Accordingly, they must rely upon sighted people to help them perform many of the activities of daily living.

One explanation for this problem has been that the traditional tests of visual function used to prescribe low-vision aids do not tell us about an individual's ability to perform everyday tasks. This information is essential for prescribing aids that allow an individual to make the most of his or her remaining vision.

The goal of our study is to apply new measures of visual function to give us an understanding of the visual environment of partially sighted persons. The measure we are concentrating on is called the "contrast sensitivity function" or CSF, which gives us an indication of how well people see details of different sizes.

We are measuring the contrast sensitivity function of partially sighted persons and using these functions to process images by computer. Theoretically, the computer-processed images will show us how the environment appears to partially sighted persons. If this is true, then we will perform additional studies to see which aspect of the contrast sensitivity function is most closely correlated with the person's ability to perform certain tasks. In the first stages of the study, we will examine simple tasks such as recognizing letters, shapes, and faces. Later, we will study more complex tasks such as those encountered in daily living.

If our study is successful, we will not only gain a better understanding of the implications of severe visual impairment, but we will also provide techniques that can be used to reduce the handicaps associated with it.

The Effectiveness of a Blind Rehabilitation Program

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Purpose — To assess the effectiveness of the Blind Rehabilitation Center, it was necessary to develop instruments to measure quality of life or life state—i.e., attitudes toward self and blindness, independence in activities and travel, and psychological state. We validated scales to measure these variables with data collected in a series of pilot tests. (The way in which these scales were to be used in the evaluation study and the way in which they fit into a general model of the rehabilitation process were described in a previous report.)

Progress — Our evaluation model required that we measure a patient's life state before he or she entered the rehabilitation program, shortly after completing the program, and again 6 to 9 months later. Since the report mentioned above, 245 patients have completed initial interviews, 190 patients have completed second interviews, and 143 patients have completed third interviews. We are continuing the data collection focusing in three areas: continued analysis of the measuring instruments' validity; preparation of the program and data for future analysis; and integration of the data into a larger data base management system.

We have constructed all of our measuring and survey instruments; most have been thoroughly tested, analyzed, and reported in the literature (see previous report). In the past year, we compared the method of scaling used in developing the measures with factor analytic techniques. We found that Rasch Scaling techniques gave stable unidimensional scales, while factor analysis gave scales of indeterminate strength, fluctuated from group to group, and, so, were too unreliable for research purposes. We revised the Attitude Towards Blindness

Scale, to make it applicable to wheelchair-bound individuals. We then completed the analysis of the validity of the activity and travel measure. While we collected data primarily to validate the activity and travel measure, our additional analyses made it possible to develop a needs assessment of the rehabilitated blind veteran.

We also have constructed two information systems for the blind rehabilitation evaluation project. Through these systems a large amount of data is collected from each patient in multiple interviews, including a demographic file, a medical history and physical exam, an ophthalmologic exam, and five separate survey instruments, each of which is administered three times. The information system to manage the flow of work and data is an easily mastered, user-friendly system that can be adapted to many types of project management. The patient information resides in a data base management system that is an industry standard DBMS with full security protection and privacy locks. It has the capacity to be used by many different programs and can easily be adapted to other research projects.

Musical Language and Large-Print Considerations in Human-Factors Engineering

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The purpose of this project is to determine the optimal cost-effective methods of interfacing the visually impaired person to computer display, digital information recovery, and entry systems.

Progress — A preliminary study has been conducted which consisted of analytical interviews with a visually impaired computer user. The recommendations which resulted from these interviews were published in a paper: Human Factors Considerations In The Development Of A Large Print Display For The Visually Impaired Computer User, published in the Proceedings of the Second Annual Conference on Rehabilitation Engineering, June 1984, Ottawa, Canada. In addition, some of the recommendations of the interview have been implemented on an Apple computer and are being tested by several visually impaired computer users. It was also suggested that the musical language be combined with the large-print displays as a means of providing bimodal display recognition. This is now being implemented and will soon be tested by several visually impaired users. The musical language referred to here was the result of a graduate feasibility study, the results of which have been discussed in previous reports.

Future Plans — The investigator intends to continue the implementation of the recommendations of the abovementioned study and further testing of these implementations by computer users under a variety of work and home situations. Finally, the results of these implementations and tests will be used as a guideline in the development of a Video Emulator Monitor and Display (VMED) for the visually impaired computer and word-processor user. The VMED is intended to be a universal device which will act as an interface between any computer and the visually impaired person.

2. Mobility Aids

The VA Guide Dog Harness

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — This is a student design project. The purpose is to design and test new guide-dog equipment made with a more appropriate choice of materials technology. The goal is to develop a harness and leash that give better wear, require less care, have superior esthetics, and cost less to produce.

Progress — Prototypes have been completed for fieldtesting and evaluation. Leather has been replaced by nylon strapping because it is lightweight, more comfortable, requires little care, and is believed to have a longer lifetime. All buckles have been replaced with Scotch-Mate, a product similar to Velcro, because it is infinitely adjustable and believed to be more comfortable for the dog. The initial harness handles were made from both acrylic and polycarbonate rod. The simplicity, practicality, and esthetics of the new harness and harness handle were rated highly by persons using guide dogs. The new handle excelled as a communication link between the dog and the disabled person. However, there have been continued problems with the handle/harness interface.

Future Plans — The cooperative testing of the VA Guide Dog Harness with several guide dog schools is currently in progress. All of the field evaluations have not been completed, but we have received many positive results, as well as some possible design improvements. When the field testing is complete we will evaluate the results and incorporate the ideas into a possible production prototype. A potential manufacturer has been located and production will follow successful testing.

SONA/SONA–ECS

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The SONA/SONA–ECS is a digital radio transmitter-receiver system that has applications for visually impaired persons as an orientation aid and for manually impaired persons as a Decentralized Environmental Control System (ECS).

Progress — Both the Sona and the SONA-ECS have proved to be highly reliable and to function well technically. SONA-ECS has had approximately 4000 hours of field testing to date, in both a work environment and a veteran's home. It is also being used to operate a door and wheelchair lift control and interior lights in a van.

The transmitter and SONA-ECS have been redesigned to simplify the hardware involved by replacing the discrete digital ICs and DIP switches with a single-chip

microprocessor and a few support devices. SONA is also being redesigned in the same manner. In addition to simplifying the hardware, the new designs will also enhance the system's capabilities, because many modifications and improvements can be implemented through software. A broader range of output devices, including input to a computer, can be easily interfaced to the system. The digital coding of the radio signal can also be expanded so that a transmitter for different uses or disabilities will send a different generic use-code in addition to the device code.

The SONA (Sonic Orientation and Navigational Aid) for the visually impaired traveler is now undergoing initial fieldtesting at the Atlanta Veterans Administration Medical Center. Response to the system has been very favorable. This initial testing involving 35 units is beginning to determine some design criteria for improvements in both the technical and human-factors areas. The use of microprocessor technology in the system will greatly facilitate the implementation of these improvements. One such improvement involves the proposed use of synthetic speech units for applications where the musical language output is inappropriate.

Future Plans — The Atlanta Veterans Administration Medical Center intends to continue development and evaluation of this system in both of its aspects. This research will focus on two areas: enhancing the performance and capabilities of both systems through the application of microprocessor technology, and evaluation of the SONA as an aid to the visually impaired traveler.

The final result of this research is intended to be the development of products which are low in cost and easily manufactured.

Design and Evaluation of Sensory Substitution Systems

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Sponsor: Catholic University of Louvaine, Brussels, Belgium; Fund for Scientific Research, Belgium; Office for Science Policy, Belgium

Purpose — For many years, the design of artificial systems for blind people enabling them to interact with visual aspects of their environment has been attempted to compensate impairments of blindness. Among the possible solutions for such artificial systems, one may use an intact sensory channel like somesthesia or audition, avoiding, on such a way, problems of long-term compatibility with implanted biomaterials. In this case, visual information has to be detected, decoded, and transmitted in the form of vibrations or sounds to the substitutive organ. Moreover, this tactile or auditory stimulation has to be correctly interpreted by the subjects, involving problems of learning and of plasticity of nervous structures. This is the theory of sensory substitution proposed by P. Bach-Y-Rita in 1972.

We are involved in a program devoted to the study of sensory substitution. Our research prospects are to evaluate this theory, by physiological means, on men and animals. To achieve that, we are following two main ways.

Progress — First, we are searching behavioral cues giving evidence of space perception enhancement obtained by using an ultrasonic binaural sensory aid roughly similar to the Sonicguide designed by L. Kay.

In these experiments we have attempted to measure, in relation to visual experience, improvements in space-perception tasks induced by this sensory aid. Space perception was studied in the grasping space and in the space of locomotion; direction and distance estimations in spatial localization tasks were recorded by means of verbal and motor responses.

Future Plans — We plan to detect possible sensory substitutions by metabolic as well as electrophysiological means.

Secondly, we focus on designing more-sophisticated visual prostheses. Our aim is to optimally design a prosthesis substituting audition to vision. This system would 1) improve spatial localization; 2) also improve performance related to other visual modalities, e.g. pattern recognition; and 3) in spite of resulting design sophistications, limit the necessary learning to a minimum of length and difficulty. These design efforts are now in progress.

Illumination and Mobility

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Sponsor: National Institute of Handicapped Research

Purpose — Among persons with low vision, the most commonly reported functional problems relate to glare and photophobia. When a person has an impaired visual system, any reduction of visual acuity can have a profound effect on both the perceived and actual ability to travel safely. This project was designed to explore the effect(s) which sunlenses have on the mobility performance of pedestrians with low vision.

Progress — Subjects were randomly placed in either a control or treatment group. Each group was required to walk a 10-block route in a residential and small-business environment. The control group did not wear sunlenses while the treatment group did. Data were collected on heart rate (measured by a heart monitor connected to a tape recorder), illumination levels, visual acuity with and without sunlenses, mobility performance, and environmental characteristics such as crowd density, temperature, and traffic density. At the completion of the project, 104 subjects had been tested.

The data are currently being analyzed. Specifically, T-tests are being utilized to determine if sunlenses provide for a difference in mobility performance as measured by heart rate, visual acuity, and obstacle detection.

Expansion of a Computerized Information System for Use in the Study of Low Vision Mobility

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Purpose — This project concerns the expansion of a computerized information system to assist researchers and practitioners in developing and evaluating theories and aids to improve mobility for low vision persons.

Progress — This project has focused on the expansion and restructuring of the Low Vision database developed and described in a previous project (NIHR, 1983)

in order to facilitate its use by researchers and patient care professionals. As indicated in a previous report (R&D, 1984), the major revisions in the data base structure, the related changes in input forms, and the development of an English-language report generator took up most of the first year. Relational modules specifically designed for projects three and four were also created. Input of patient and subject information was continued.

The input of patient and subject information has been continued into the last year of the grant. The O&M modules have been finalized and put into use by projects three and four. In addition, programs designed to analyze the data have been developed and refined. These programs have been used for generation of demographic information, for interfacing with statistical and exploratory analysis software packages, and for tabulation of clinical data associated with use of specific aids. The latter is being used in the evaluation of low vision aids through study of the patterns of their issuance. In addition, evaluatory protocols for use by Eye Care Professionals in the individual assessment of various types of mobility related, low vision aids have been developed.

The Effects of Low Vision Aids and Training Methods on Mobility Performance and Stress

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Purpose — To determine the effects of low vision aids, and traditional versus non-traditional training methods, on the independent mobility performance and stress levels of individuals with low vision.

Individuals with reduced vision experience more stress (as measured by increased heart rate) in mobility than their fullysighted counterparts. Traditional mobility training techniques have not addressed the mobility needs nor the higher stress levels of individuals with low vision. The use of low vision aids combined with orientation and mobility training and relaxation techniques will lower heart rate and reduce mobility-critical events as well as self-perceived stress levels of subjects during mobility situations. In addition, overall self-image will be improved.

Progress — Forty subjects were selected who met the following criteria: 16 years of age or older; metropolitan Philadelphia residents; with mobility problems; with enough residual vision to benefit from a telescopic device; and with adequate health to walk a 10-block route.

All subjects received the following: 1) comprehensive low vision evaluation consisting of social intake and history, acuities, fields, ocular health, blood pressure, color testing, sun lens evaluations, and optical aid evaluation; 2) 1 hour of training with a telescope; 3) a 10-block mobility screening during which heart rate was recorded and mobility "critical events" (problems) were noted; and 4) administration of a battery of seven questionnaires measuring attitudes about low vision mobility, stress in general, stress related to mobility, psycho-social status, and attitudes about blindness.

All subjects recorded their experiences in a journal. All subjects were randomly assigned to one of four treatment groups, with maximum of 10 per group.

Group A received the telescope, a maximum of 30 hours mobility training incorporating use of the telescope, and 10 hours of relaxation training over a 7-week period.

Group B received the telescope and 30 hours of mobility training incorporating use of the telescope over a 7-week period.

Group C received the telescope and 10 hours of relaxation training over a 7-week period.

Group D received the telescope for a 7-week period.

At the end of the 7-week period all subjects returned for post-testing and to submit their journals. Post-tests consisted of the following: Optometric (acuity, fields, color testing, and blood pressure); Psycho-Social (battery of questionnaires); and Mobility (a similar but different 10-block route while heart rate and mobility critical events were recorded).

Preliminary Results — Preliminary findings yield trends showing varying degrees of improvement in mobility in Treatment Groups A, B, and C: no change and even regression is shown in Group D. Results will be analyzed and reported.

The Spatial Orientation of Low Vision Persons

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Purpose — This project is about the spatial learning and orientation of low vision persons. Spatial learning and orientation were assessed in terms of the accuracy of observers' judgments of the spatial relations learned among the important landmarks of 4×4 block business and residential districts where they had traveled extensively. The participants were asked to judge the following from memory: the straightline and walking distances among landmarks, the heading to landmarks from three different points of observation, and the two most efficient routes connecting three pairs of landmarks. The 91 subjects included 79 with low vision, six with no vision, and six with normal vision. The low vision participants varied in their etiologies, type of remaining vision, and age of onset.

There were three specific aims of this study. One aim was to develop procedures to assess the spatial learning and orientation of low vision persons and to examine the reliability and validity of the measures. The odd-even item correlations computed to assess reliability were good, ranging from 0.70 to 0.90. To assess validity, a multitrait-multimeasure approach was used. The pattern of correlations across different methods of measuring the same thing and across similar methods of assessing different things indicated good validity.

The second aim was to assess variations in spatial learning and orientation as a function of the participant's type of low vision and age at onset of visual loss. Preliminary analyses indicate that type and onset of visual loss play little role in participants' judgments of routes they have learned. However, they indicate that people with early onset of visual field loss, but not early onset of acuity loss, error greatly at judging straightline distances and directions, abilities thought important in devising new routes and helping learn a new space. And, finally, the third aim was to investigate the effect of age, amount of orientation and mobility teaching, and demographic factors on the spatial judgments.

The Mobility of Persons with Low Vision

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Purpose — The aim of this project is to access variations in mobility in novel situations as a function of variations in the person and in the situation. The major person variables are acuity, contrast sensitivity, visual field size, and amount of formal mobility training. The major situational variables are level of ambient illumination, nature of the space, and specific environmental feature to be navigated. The 42 adults who participated included 30 with low vision, six with light perception or less vision, and six with normal vision.

Progress — Although data collection is complete, the results are not yet available. The remainder of this abstract outlines the project's methods and specific aims.

During the tests, participants walked routes in 3 unfamiliar places: an office building (0.2 mile), an outdoor business district (0.7 mile), and an outdoor residential district (0.7 mile). Their primary task during the walk was to travel efficiently and safely. To evaluate primary task performance, their travels were continuously videotaped. The tapes were later scored to count the number of collisions, stumbles, pauses, changes in rate, changes in gait, and other incidents. In addition, participants performed a secondary-choice reaction time task while walking; errors and latencies on the secondary task were recorded as well. Participants walked each route two times, once under normally bright levels of illumination and once under dim illumination caused by wearing 1-percent wraparound filters. Participants' vision was assessed in terms of Snellen acuity, contrast sensitivity to sinewave gratings ranging from 0.25 to 28 cpd, modified bowl perimetry, and confrontation perimetry.

One specific aim of this project is to identify specific features of environments that are problematic for persons who have specific types of low vision. The second specific aim is to relate variations in level of ambient illumination to specific travel difficulties. The third specific aim is to investigate the relation of variations in visual field size, acuity, and contrast sensitivity to variations in the level and kind of difficulty encountered when traveling in each of the specific situations.

Measuring the Mobility of Blind Travelers

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — To conduct a valid evaluation of a blind mobility training program, you must be able to sufficiently measure the effect of the program on the blind traveler. In the past, two different approaches have been used to measure the blind traveler's mobility: 1) a measurement of the travel skills of the traveler; and 2) a determination of the amount and type of travel for the traveler.

Preview efforts in both types of measurements have been less than optimal. In addition, researchers have never compared the measures to each other. Thus, the relationship between travel skills and travel behavior is unknown.

Progress — Recent improvements in the two measures now make it feasible to study that relationship. One of these improvements is the use of a portable, ultra-

sonically based gait-measuring system, developed at the Hines VA Rehabilitation R&D Center. This system measures the traveler's step length, time, and cadence while walking. The other improvement involves the use of a more psychometrically valid questionnaire for assessing the travel behavior of the blind person.

Our study measures the travel skills and travel behavior of two groups of veterans: low vision travelers and blind travelers. We are measuring the travel skills with the interankle distance measuring system and the travel behavior with the Travel Inventory. We are measuring the skills and behavior on four occasions; twice prior to training and twice after.

Once we have gathered the measurement data, we will assess the relationship between these two sets of measures and across the four measurement points. It is hypothesized that the level of travel behavior at the fourth measurement will not be fully explicable in terms of the acquired travel skills. There are other factors in addition to travel skill that affect actual travel behavior.

Evaluation of Travel Skills of Visually Impaired Veterans

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Purpose — At the present time, there is no universally accepted evaluation procedure for the performance of orientation and mobility by blind and partially sighted subjects. This has serious implications in terms of progress and device evaluation, as well as for documentation of patient progress.

To address some of these concerns, NIHR is currently supporting the development of an orientation and mobility evaluation protocol at the Pennsylvania College of Optometry (PCO) Research and Development Center.

Progress — The investigators in this project, through cooperative efforts between the VA's Eastern Blind Rehabilitation Center and the College, have been actively involved with the development of this protocol, which has been fully implemented and is now in use at PCO.

While the population sample at PCO is large and potentially representative of the visually impaired population of the United States, there are basic differences related to gender, visual history, and secondary conditions between this population and that served by the Veterans Administration. This project seeks to adapt the O&M evaluatory protocol to accommodate these perceived differences in the population as seen at these two locations and to integrate and extend the number of subject scores contained in a cumulative database.

Future Plans — In the course of implementing this project, the O&M staff will be in-service trained on the exact protocols and data-collection techniques. This will directly involve the entire O&M staff with an ongoing research and quality-assurance project. By doing this we will not only quantify the measurement of O&M problems experienced by veterans, but also the measurement of O&M services delivered to this population and their remedial effects. In addition, we will increase the level of instructors' awareness of, and abilities in, implementation of research methods.

As we have documented, previous endeavors by research groups have theorized about the evaluation of O&M but have done relatively little to implement their ideas with a large subject pool. This research will implement at the EBRC an evaluation protocol which was developed by professionals from a variety of disciplines and experiences. Most important is the commitment to obtain data on a large sample so that, as deficiencies in the protocol become apparent, extensions of the protocol can be developed and implemented.

Development of a Graphic Braille Display

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Sponsor: VA Rehabilitation Research and Development Service

Purpose—Computer access for the blind and partially sighted has become of increasing concern within the rehabilitation community because of the economic and educational promise of this technology. A major, unresolved concern is access to graphic information. This information includes charts and graphs, schematic diagrams, accounting tables, and other information necessary in the day-to-day use of computers. This proposal has the goals of developing a two-dimensional, tactual display useable by the visually impaired, and the development of software necessary to interface the display with many common computers. These computers include the Apple IIe, IBM PC, and the Data General One.

The American Foundation for the Blind estimates that there are some 2 million blind and partially sighted persons in the United States. Estimates based upon incidence and prevalence rates supplied by the National Center for Health Statistics and census data from the Veterans Administration indicate that there are some 267,000 severely visually impaired veterans. Most of these veterans are age 60 and above, however approximately 60,000 are age 55 or younger. These veterans have potential working careers of 10 or more years.

Computer access is a clear necessity for many vocational and educational opportunities today, and it is clear that over the next decade many more opportunities will require computer access. Current estimates are mixed; however, it appears that perhaps as many as 50 percent of all jobs now require some interaction with a computer. By the year 1990 it is estimated that 80 percent to 90 percent of all jobs will involve interaction with a computer. A major component of the expanded use of computers will be the use of graphics to display information. Graphic displays may be used to highlight particularly important messages, to concisely display complex information (e.g., pie charts), to represent complex commands (e.g., icons), to improve the aesthetics of visual displays, and for a variety of other uses. The use of graphic displays poses a potential problem for visually impaired computer users.

The most common means used by the visually impaired to access computers are synthetic voice, single-line refreshable braille displays, hard-copy braille printers, low vision aids, and large print computers. Synthetic voice output from computers is an inexpensive means of attaining access; however, it does not allow access to graphic information. Single line refreshable braille displays do not provide access to graphic information. Hard-copy braille printers provide access to two-dimensional graphic information, but their slow printing speed does not

allow their use in interactive situations. Large print computers currently allow access only to alpha-numeric information. Low vision aids can be used by some partially sighted individuals to access conventional graphic displays and in these cases represent an effective, low cost solution. However, it currently appears that low vision aids are effective for only a small percentage of the visually impaired population.

Blind and partially sighted individuals have a clear need to access computers and computer-based information. Such access is critical in attaining education and in securing and maintaining employment. The inability to access graphic information represents a severe limitation to computer access. The current project seeks to ameliorate this situation by developing a relatively low cost graphic display system and the necessary software to interface it with commercially available computer equipment.

Progress — Over the past years the American Foundation for the Blind, under the direction of Mr. Doug Maure, has been developing a low cost, graphic and braille display. The mechanical design of the display is well advanced; however, several key questions remain. These concern the human factors design of the device and the development of software to support the display. Solutions to these concerns will be followed by the dissemination of all design information to a suitable manufacturer.

Resources available are the Western Blind Rehabilitation Center, the American Foundation for the Blind, and the Veterans Administration Medical Center in Palo Alto, which also houses a Rehabilitation Research and Development Center which provides a locus for biomedical engineers, physicians, psychologists, and others interested in developing technology to assist the disabled. Academic affiliations of the above include Stanford University, University of California, Berkeley, San Francisco State University, Western Michigan University, and California State University, Los Angeles.

The subject population for the project will be drawn from three sources: 1) staff of the Western Blind Rehabilitation Center include totally blind and partially sighted experienced computer users. These individuals constitute an "expert" subject population which will be used for initial testing and debugging of hardware and software; 2) the veteran population attending the Western Blind Rehabilitation Center includes numerous individuals motivated to learn computers, but who are relative novices. These individuals will be used as subjects in studies designed to test the ease of use of the display and associated software; 3) the local community contains many blind individuals who currently use computers in day-to-day work situations. These individuals will be used to assess the function of the braille display and software in actual work environments.

There are three primary areas to the current project: hardware development of the display, software development, and human factors evaluation of the display and software.

Delivery of the first prototype display module (from the American Foundation for the Blind in New York) occurred in March 1985 and was followed by a 2-month period of familiarization for the Palo Alto investigators and preliminary software development. The prototype display had uniformly high quality braille; however, the refresh rate was slow, requiring 4 to 5 minutes to completely refresh

the display. The second prototype is expected to be considerably faster with an expected refresh rate of 40 to 60 seconds per page. In June 1985 concurrent development of graphic software and human factors evaluations will begin. Initial software development will be geared to providing necessary software for the human factors studies. These studies will provide information on legibility of the display, reading rates, fatigue factors (if any), and will result in design recommendations for future prototypes.

Future Plans — The above studies are expected to continue through the first year of the project. Concurrent with them will be the attempt to develop additional capacities for the braille display. These capacities may include the addition of a dedicated keyboard, voice synthesizer, and printer I/O ports. Purchase of the components necessary to support these capacities has begun and development work will continue into the second year of the project. At present, since such features will increase the cost of the display, they are conceived of as "options," That is, when the display is manufactured it may behave in an analogous manner to a "dumb terminal." However, the consumer would have the option of increasing its capabilities.

During the second year of the project final recommendations to the design of the display will be made if appropriate; however, the primary emphasis will be on the development of application software. This will be facilitated by testing the software within the context of the Western Blind Rehabilitation Center which provides both experienced and novice computer users, and by testing in actual job settings.

Upon completion of the project it is expected that the display with application software will be sufficiently advanced so that it can readily be turned over to a manufacturer. By developing the hardware and software through non-profit and government grants, much of the development cost that would normally have to be passed along to the consumer can be defrayed. This will minimize the ultimate cost of the display and make it a more economical and more widely used aid than would otherwise be possible.

The Effects of Preview Distance on Blind Mobility

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Sponsor: VA Rehabilitation Research and Development Service (R&D Center Core Funding)

Purpose — The objective of this research project was to establish boundaries for the effective preview distance for blind pedestrians. Using an ultrasonic ranging device, we did this by systematically varying the preview distance for a group of experienced, blindfolded travelers walking over a predetermined course six times.

Progress — The first time the group walked over the route, we used no preview device and we placed no movable obstacles on the route. This trial familiarized the traveler with the route and gave baseline data on walking speed, step length, cadence, etc. In the remaining trials, we placed movable obstacles randomly along the route, and each subject had the preview device along.

For the test, we used a modified version of a Polaroid ultrasonic ranging device, setting it to a predetermined preview distance for each subject in each trial. This distance varied from 1 foot to 10 feet. Half of the subjects had increments of even distances (2,4,6,8, and 10 feet) and half had odd distances (1,3,5,7, and 9 feet); also, half of the subjects had ascending preview distances over their five trials and half had descending distances.

We measured the mobility behavior of the subjects with a gait-measuring system developed at the Hines Rehabilitation R&D Center; the system provided data on interankle distance over time. From these data, we were able to determine measures such as step time, length, and cadence for the entire route and parts of the route (e.g., at obstacles).

Currently, we are analyzing the data. Of interest will be the effect of the differing preview distances on the gait characteristics of the travelers, particularly the distance or distances at which degradation in performance occurs.

Development of a Solid-State Reading Aid for the Visually Impaired Person

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Purpose — Blind and partially sighted individuals need an affordable, portable, and versatile reading aid that gives them access to printed materials such as newspapers, magazines, and typescript pages. Blind access to printed materials is currently limited under the three available approaches: 1) using specially-prepared materials (Braille books, "talking books" on cassette tapes); 2) employing electronic reading aids, such as the expensive Optacon (which allows the user tactually to feel the shape of letters), the occasional Stereotoner (which produces chords of tones from the shapes of letters), or the copier-sized Kurzweil Reading Machine (which reads the text in synthesized voice output); and 3) engaging the services of sighted readers. Each of the current approaches has drawbacks: Braille materials are bulky and expensive, and cover only a small fraction of inkprint materials; cassette recordings are typically available only for mass market items, such as popular novels, but not for newspapers, magazines, technical publications, personal letters, etc; Kurzweil Reading Machines are expensive and cannot be moved by a single person; and older persons with failing eyesight are typically unsuccessful in learning to use the Optacon. Sighted readers perform well, but they are expensive and not always available at users' convenience. In all, there is a need for a portable, easy-to-use, and affordable reading machine that can communicate to the user using the mode of his choice (e.g., voice output, Optacon display, enlarged letters).

The objective of this project is to produce a working prototype of a compact and affordable reading device, specially designed to meet the needs of visually impaired individuals. This device will comprise the following major components: 1) a hand-held camera which the user can track over inkprint to capture an optical image of the printed characters; 2) a microprocessor to carry out image processing and optical character recognition, and to drive the output displays; and 3) a special

interface board, to provide plug-compatibility for this device with commercial products already widely used by the visually impaired community (e.g., the Optacon, the Stereotoner, enlarged print displays). In addition, the device is designed to be plug-compatible with commercially available speech synthesizers and with home computers.

Progress — Our approach is to employ contemporary technology innovatively to meet our objectives. Our hand-held camera, for example, utilizes an Optic RAM (Random Access Memory) for image capture. This solid-state imaging device, only recently on the market, is inexpensive, compact, durable, operationally fast, of high resolution, and able to alter its imaging window under software control. The image is brought to the Optic RAM by two types of fiber optics—a demagnifying component, and a Selfoc (self-focusing) fiber optic "lens." The fiber optics contribute to keeping overall dimensions down. Illumination is provided by light emitting diodes (LEDs), which are compact, rugged, of low power requirements, long-lasting, and cool to the touch. Printed circuit boards and hybrid chip technology allow reduction in the support circuitry layouts for the Optic RAM and LEDs, making a hand-held unit feasible. A special Optic RAM controller board services the Optic RAM, acquires data, packs them efficiently into bytes, and deposits them directly into memory, all without burdening the device's microprocessor. An advanced, 16-bit MC68000 microprocessor interprets the data, executing algorithms written in C (a high-level programming language) and in assembly language for speed and efficiency. A special interface board, built upon an Intel 8085 microprocessor, provides plug compatibility with the Optacon, the Stereotoner, and a TSI Enlarged Display Light Box.

We are very close to having a first working laboratory prototype of reading aid operational. The electronics for the hand-held camera on PC board have been constructed, along with the mountings for the optics and the imaging units, and workings of these components in capturing an image have been verified. The Optic RAM controller board has recently been completed and is available for integration into the laboratory prototype. With the incorporation of the LEDs for illumination, we will have the front end of the device operational. Algorithms have been written and tested for automatic thresholding of the device; for character location, isolation, and normalization; and for a template-matching scheme of optical character recognition. The output interface board was completed and displayed at RESNA in June 1984, and awaits incorporation into the final device.

A Large-Print Word Processor for the Visually Impaired Person

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The large-print word processor is a generic equivalent of cassette-braille machines designed for large-print users. The system features a large-print display and typewriter keyboard with microcassette storage of information.

Progress — Construction of prototype test units has been completed. There are currently two units in working order. This system is based upon the Typecorder, a

battery-powered portable Sony word processor. The Typecorder has been modified to accept an intelligent interface and a large-print display suitable for use by visually impaired persons.

The new system was designed as an electronic add-on and is plug-compatible with the Sony LCD display. The Typecorder interfaces with a new display, the Deco 245A. It is a vacuum tube fluorescent display with a standard ASCII character display set. To connect the Typecorder with the Deco display, an interface circuit was built. This interface had to transform the Typecorder's cursor instructions into instructions recognized by the Deco display. Those two functions are handled by the Intel 8741 peripheral controller. A third function of the interface is to provide electrical isolation between the CMOS circuitry of the Typecorder and the TTL circuitry of the Deco. That electrical buffering is handled by Motorola MC14503 buffers.

The completed prototypes now offer an alternative display with 40 characters of 0.2 inch height. The display is of high resolution and considerable brightness. Preliminary tests indicate it to be of great value to the population that needs it, at a reasonable cost when compared to the alternatives. The problems remaining include the provision of reading material on the Sony microcassette format, and the legal questions involved in any such attempt.

Future Plans — Work will continue to locate a suitable manufacturer for this product.

The Evaluation of Low Vision Aids and Prediction of Visual Performance Through Low Vision Aids

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Sponsor: National Institute of Handicapped Research

Purpose — The goals of this study are to evaluate the optical properties of low vision telescopes and telemicroscopes, and to determine which objective measures of optical performance are the best predictors of visual performance through the aids. The optical evaluation of the low vision aids will include measuring their modulation transfer functions (MTF), resolving power, angular magnification, field of view, eye relief, exit pupil diameter, and, finally, light transmittance.

Visual performance in normal sighted and visually impaired subjects will be assessed by measuring their contrast sensitivity functions (CSF). The CSF is the visual analog of the modulation transfer function. It is a subjective measure of visual sensitivity across an entire range of spatial frequencies. Contrast sensitivity functions may reveal visual disturbances that are not evident from acuity testing, perimetry, or other clinical examinations. The CSF quantifies a visual deficit that may correlate with the patient's own subjective complaints or explains visual complaints that some patients find difficult to express. It is thus likely to have predictive value in assessing visual performance through low vision aids. The effect of the modulation transfer function on the contrast sensitivity function promises to provide an important criterion for specifying and prescribing the most beneficial low vision aid.

This study will provide, for the first time, detailed specifications and optical

quality measures for low vision aids that will reveal how well each manufacturer controls quality, and how aids of different manufacturers compare.

We will optically evaluate low vision telescopes and telemicroscopes to determine their modulation transfer functions, resolving power, and such paraxial properties as field of view, angular magnification, eye relief, exit pupil diameter, and light transmittance. A computerized database containing these measurements will be established. The database will be accessed to compute figures of merit for comparing the low vision device and to select devices for visual tests. We will also develop optical performance standards for low vision aids.

Low vision subjects generally will include, but not be limited to, individuals of all ages referred by the low vision clinics of the NYAB and the College of Optometry.

Progress — At the time of submitting this report, the design and fabrication of modulation transfer function apparatus is nearly complete, as are modification to measure contrast sensitivity functions through optical devices.

A "Moon" Writer

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Sponsor: Research Centre for the Education of the Visually Handicapped

A report published in the New Beacon for July, 1984 (Vol. 68, No. 807, pages 173–176) is an account of the evaluation of a portable device which enables blind people to write Moon, a raised-line reading system designed in the 19th century by Dr. Moon. Moon is widely used by the elderly in Great Britain if their tactual ability makes braille difficult to learn.

Until the invention by Mr. Gerd Sommerhof of the Moon Writer, the use of Moon for everyday purposes (such as the labelling of household goods or the writing of shopping lists) was impossible, since Moon could only be produced by large machines required for the wetting and subsequent drying of the heavy-duty paper on which it is embossed. The evaluation described in the report involved teaching sighted people and blind people who did not know Moon, and skilled readers of the system. It was concluded that the "device is the most promising mechanical advance in the 40-year history of the Moon system (and has) the potential to transfer Moon into a reading and writing system."

Speech Transmission Laboratory: Quarterly Progress and Status Report

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Sponsor: Royal Institute of Technology

The Quarterly Progress and Status Report (QPSR) of the Speech Transmission Laboratory for January through March, 1985, carried the following individual reports in the subject areas noted.

"Speech Production: Dynamic Line Analogs for Speech Synthesis," by Johan Liljencrants.

"Speech Analysis: Analysis of Spoken Digits — Project Liisa," by J.U.J. Stålhammer, and "Glottal Wave Forms for Normal Female Speakers," by Inger Karlsson.

"Speech Recognition: Automatic Time Alignment of Speech With a Phonetic Transcription," by Mats Blomberg and Kjell Elenius; and "A Parallel Speech Analyzing System," by Rolf Carlson, Björn Granström, and Sheri Hunnicutt; and "Phonetic and Orthographic Properties of the Basic Vocabulary of Five European Languages," by Rolf Carlson, Kjell Elenius, Björn Granström, and Sheri Hunnicutt.

"Speech and Hearing Defects and Aids: The Use of a Synthesis-by-Rule System in a Study of Deaf Speech," by Anne-Marie Öster.

Reading Aids for Blind Readers

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Sponsor: Hines VA Research and Development Center, (Core Funding)

Purpose — Reading with the Optacon: We examined the manual scanning patterns and reading rates of a population of blind optacon readers. The results provide baseline measures for this type of reading. Similarities to sighted reading were a surprising result, providing a basis for speculation regarding the dramatic difference between sighted and blind reading rates.

Inkbraille: We are exploring the possibility of using printed braille as a medium be read by means of a simple inexpensive electronic reading aid. Braille reading rates are the highest achieved by the blind. The economics to be realized by printing, rather than embossing, braille patterns are considerable. We have begun pilot experiments to determine if blind subjects can read Inkbraille at rates higher than those observed, e.g., with the Optacon. Preliminary design work is underway on a device to translate Inkbraille to a suitable tactile pattern.

"Magic Wand," The Braille Teacher

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Sponsor: Hines VA Research and Development Center (Core Funding)

Purpose — Learning braille is a difficult task. It is like learning a foreign language, but harder because you must learn to read with your fingers. We have made learning braille easier by adapting a consumer product by Texas Instruments called the "Magic Wand Speak and Learn."™ The Magic Wand was designed to help children learn to read by associating printed and spoken words. It uses special books that contain text and bar code. When the "Magic Wand"™ is passed over the bar code, the text is converted to synthetic speech.

Progress — We adapted the Magic Wand™ books for braille teaching by simply placing braille over the text and adding tactile symbols to make it easy to find the bar code. With our books, students can easily study braille by themselves without help from either a braille teacher or sighted person. This not only gives them more independence, but also gives braille teachers more time to help students.

We are now working with Texas Instruments to develop books specifically for teaching braille to children and adults. These will be distributed to public and private rehabilitation organizations for evaluations.

B. Deafness and Hearing Impairment

[*See also pgs. 273, 283*]

Studies in Acoustic Feedback in Hearing Aids

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The causes of acoustic feedback in hearing aids are not well known and the remedies for it are limited. The objectives of this project are 1) to study the mechanisms which facilitate unstable acoustic feedback and to determine the key physical and electrical parameters and interactions which affect it, 2) to study several earmolds designed to reduce acoustic feedback and thus provide greater electroacoustic gain to the user, and 3) to build and test several prototype hearing aids incorporating circuitry that successfully suppresses unstable acoustic feedback.

Progress — Mathematical models of hearing aid microphones, amplifier/receiver, and the feedback path from earmold vents to the microphone have been developed. The results of computer simulations using each of these models compared favorably with experimental data. These models have been incorporated into a computer program for simulating the open-loop transfer function of *in situ* hearing aids. A comparison of the computer simulation with experimental data indicates that the computer provides accurate simulation of open-loop-transfer function data.

Two earmold types have been evaluated for their ability to provide additional stable gain to the hearing aid user. First, earmolds were obtained from 10 ears using Reprosil, a dental impression material. A hermetic seal of the impression in the ear canal was verified by using the air pump of an electroacoustic impedance bridge. The impression was sent to a commercial laboratory for the fabrication of the final ear piece. For 9 of the 10 years, a hermetic seal was obtained when the finished ear piece was returned from the laboratory. Functional gain measurements showed that for frequencies below 1 kHz an average 5 dB additional gain was obtained with earmolds fabricated in this way, and that an average of 20 dB gain was obtained in the frequency region of 3 kHz.

The second earmold type was developed by the National Acoustic Laboratories in Australia. This vented earmold contains a tube which terminates at the tip of the earmold with its other end terminating in a cavity in the concha section of the earmold. This design creates a high-cut acoustic filter for sounds emitted from the vent outlet. Earmolds of this type have been fabricated for 10 hearing aid users. Studies of insertion gain and of the open-loop-transfer function with this and an acoustically comparable standard, vented earmold are in progress.

A microprocessor-based feedback suppression system was developed. This system uses a technique known as active feedback cancellation (AFC). In the original version, the system used a pseudo-random noise generator to insert a low-level noise into the hearing aid circuit. That portion of the PRN which returns to the microphone is monitored. A microprocessor uses the original and the feedback PRN signals to compute the open-loop-transfer function of the hearing aid. In the

AFC system, a microprocessor uses the computed values to create an "estimator" which causes input signals to react destructively with signals returning through the feedback path, thereby cancelling the effect of the feedback signal. In the latest version, the need for pseudo noise to measure the open-loop-transfer has been eliminated and, additionally, the current AFC system is more compatible with the power requirements of the body-worn hearing aids. The current effort is to miniaturize the AFC system so that it can be incorporated into a head-worn hearing aid chasis.

Development of Materials for Computer-Assisted Instruction in Lipreading

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — A computer system has been designed and software has been written for an auditory-visual laser videodisc interactive system (ALVIS) for drill and practice in computer-assisted instruction in lipreading. The system includes a laser videodisc player, a microcomputer, a keyboard, a video monitor, two microfloppy disk drives, a dot-matrix printer, an external amplifier and attenuator, a programmable attenuator with associated accessories, and earphones.

The goal of this program is to examine the effects of supplementary drill and practice with an auditory-visual laser videodisc interactive system (ALVIS) on the development of lipreading skill.

Progress — Twelve lists of 25 sentences each have been standardized and arranged in order of difficulty from easiest to most difficult as lipreading stimuli. These five- to eight-word sentences, presented in order of difficulty, were recorded on 1-inch videotape and then pressed on videodisc. Presentation of the 300 sentences is under software control by ALVIS in each of two conditions. In the first condition, word clues are presented on the video monitor for a maximum of five trials. The presentations of the lipreading stimulus in this condition are given with no sound. By the fifth presentation, three clue words are given on the video monitor.

In the second condition, auditory clues accompany the visual stimulus for a maximum of five trials. The first presentation of the sentence is given without sound. If this presentation is not identified correctly, on the second trial the student receives the auditory signal via earphones at 0 dB in relation to his binaural speech detection threshold. For the third, fourth, and fifth trials, the sensation level of the auditory signal is 5 dB, 10 dB, and 15 dB, respectively.

Each student has his own microfloppy disk. Responses during the drill are recorded, as are the number of words lipread correctly, the number of seconds taken to respond, and the total number of trials required for each sentence. In addition, the subject's identification data, hearing test data, and lipreading practice data with computer-assisted instruction are recorded on the student's disk.

The auditory-visual laser videodisc interactive system (ALVIS) is being used experimentally in a program of aural rehabilitation which includes lipreading instruction for postlingually hearing-impaired adults. Six subjects receive group lipreading lessons twice per week for 6 weeks. On days following group

instruction, each of two subjects receives lipreading drill and practice in one of three conditions: 1) with ALVIS word clues, 2) with ALVIS auditory clues, and 3) with face-to-face drill and practice with the lipreading instructor. Thus far, 2 groups of 5 subjects each have completed a total of 12 group lipreading lessons and 12 individual drill and practice. By the conclusion of this phase of the project, 36 subjects will have participated in group lipreading instruction: 12 will have received drill and practice with ALVIS clue words; 12 will have received drill and practice with ALVIS auditory clues; and 12 will have received face-to-face drill and practice with the lipreading instructor.

Clinical Trial with the Cochlear Implant Prosthesis

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — This project was designed to develop assessment methodology and evaluate the rehabilitative effectiveness of the 3M-House single-channel cochlear implant as a treatment for profound sensorineural deafness. The work is now in the second of a 3-year grant period.

During the first year, a team of highly qualified specialists in hearing, speech, voice, and language was assembled; and the methods and procedures for determination of cochlear implant candidacy were developed, including generation of new high-quality color videotapes of speechreading, new recordings of auditory tests of speech perception, and a new scale of beliefs concerning deafness. Software to permit psychoacoustic procedures detection (discrimination and masking experiments) was created.

The full evaluation protocol entails: audiologic examination with and without hearing aids; psychoacoustic measurement; communication and handicap assessment including speechreading measurement and trials with a vibrotactile device; voice and speech recording; medical examination; otologic evaluation; tomography of the cochlea; optometric examination; and psychologic and neuropsychologic evaluations.

Progress — Candidates were solicited by announcing the program in letters to the VA and broader professional community and with statements in the printed and broadcast media. As a result, a subject pool of prospective candidates to be evaluated was established.

In the second project year, profoundly hearing impaired subjects were screened and possible candidates were fully evaluated. To date, 21 profoundly impaired men (19) and women (2) have been tested. The trials are still in progress, with 3 patients having been implanted and 5 more surgeries pending. Outcomes for the non-selected subjects were prescribed: tactile aids (2); new hearing aids (4); aural rehabilitation with current hearing aid arrangement (1); medical treatment referral (2); geriatric unit evaluation referral (2); and controls (2).

Preliminary Results — Data derived thus far have lead to the following submitted reports, among others: 1) single-channel cochlear implant enhancement of contrastive stress; 2) contrastive stress in an adventitously deaf adult using vibrotactile stimulation; 3) recognition of voicing and nasality by deaf adults

using vibrotactile aid or cochlear implant; 4) standardization of videotaped tests of speechreading ranging in task difficulty; 5) aural rehabilitative guidelines for the adult with a cochlear implant: case reports.

Implementation of Digital Measurement of Aural Acoustic Immittance

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Work during the first full year of the project (May 1984 to May 1985) has provided necessary experience with the programmable digital device and allowed development of reliable programming techniques and development of software.

Progress — Software systems have been devised for labeling, storage, reduction, and graphing of tympanograms and individual (contralateral) acoustic-reflex responses acquired with a 226-Hz probe tone and expressed in both components of acoustic admittance (Y_a). The reduction routines include automated computation of amplitude and phase from the tympanogram, plus measures of amplitude, latencies, and onset-offset characteristics from the acoustic reflex response. The graphics software creates plots of individual or stacked tympanograms or acoustic reflex responses. These software systems have been used to collect data for an investigation report, and much of the software is illustrated in a recent article submitted for publication. Other efforts have included evaluation of methods of measuring the time constant of a digital acoustic immittance instrument, development of communications between computers (Tektronix 4052 and IBM-PC) for convenient data transfer, and configuration of acoustic immittance data for access by commercial statistical software.

Future Plans — Work planned for the coming year includes development of additional software for measurement of the acoustic reflex response and acquisition of data from normal ears and ears with hearing impairment.

Direct Measurement of Loudness Recruitment in Hearing Impaired Veterans

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The main objective of this investigation is to further develop, test, and ultimately standardize a direct psychophysical scaling procedure for the measurement of loudness recruitment in a routine clinical setting. Particularly important is the potential to distinguish between cochlear and retrocochlear pathology.

The subjects will be volunteers recruited mainly from the adult veteran population with cochlear impairment and with visual performance of 20/60 or better. The participants, all with bilateral hearing losses, will be subdivided into three groups on the basis of their pure-tone audiograms. The groups will consist of those with mild–moderate losses, those with severe losses, and those with profound losses. From 20 to 30 listeners will be included in each subgroup; in

addition, from 6 to 8 listeners with unilateral cochlear impairment in each of the 3 hearing loss groups will participate in the study. Twenty listeners with normal hearing will serve as a control population.

First the subjects receive a complete otological examination and audiological evaluation. After the initial assessment process, which also includes a visual screening test, loudness in the impaired frequency region will be measured primarly by the direct psychophysical scaling procedures of absolute magnitude estimation, absolute magnitude production, and cross-modality matching. A limited number of alternate binaural loudness balances between a tone in the normal ear and a tone at the same frequency in the opposite, impaired ear will also be performed.

Preliminary Results — No results are, as yet, available. Progress has been made in three areas: 1) organization and arrangement of existing laboratory equipment and ordering of new, specialized equipment; 2) assembling a professional staff; and 3) discussions and consultations with the Departments of Audiology and Optometry at the VA outpatient clinic dealing with the establishment of auditory and visual guidelines to be followed in the selection of subjects.

Phoneme Confusions Associated with Room Reverberation, Age, and Hearing Loss

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Sponsor: National Institute of Neurological and Communicative Disorders and Stroke

Purpose — This study will deal with phoneme errors associated with room reverberation (T), one of the most common distortions of speech in everyday life. In the first part, effect of reverberation on speech understanding by subjects from various age groups will be tested with Modified Rhyme Test. Three Ts, ranging between 0.5 and 1.5 seconds, typical for offices, auditoriums and churches, will be used. Age range of subjects will be from 20 to 70-plus years. Subjects will have normal hearing or mild hearing losses. Dependence of speech understanding on age and T will be established.

In the second part, phoneme confusions associated with reverberation will be investigated for subjects with various configurations of hearing loss. Range of T will be between 0.25 and 0.75 seconds, typical for small offices, classrooms, and living quarters—common everyday listening environments of hearing-impaired listeners. Two separate tests will be constructed: 1) sentences with nonsense syllables to test identification of 16 consonants in initial and final positions, and 2) sentences with one-syllable words to test identification of 15 vowels. The pattern of errors will be established for four groups of subjects: 1) with normal hearing, 2) with mild flat losses, 3) with sloping losses, 4) with moderate to severe flat losses; for consonants in initial and final positions and for vowels at three Ts.

Since a small number of vowel errors is anticipated, change in the quality of vowels (timbre) will also be investigated. Each vowel recorded at three Ts will be cut off from the test word and compared with its own non-reverberant pattern. Similarity judgments will be obtained using a seven-point scale. All tests will be recorded, processed through a reverberant field, and reproduced for subjects through a loudspeaker. The study will assess speech perception difficulties in reverberation by elderly hearing impaired listeners.

This information can be used in counselling, auditory rehabilitation, and as a guideline for developing clinical procedures including reverberation as a parameter. This parameter may improve hearing aid fitting and initial acceptance of aids by patients.

Communicative Disorders Clinical Research Center

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Sponsor: National Institute of Neurological and Communicative Disorders and Stroke

Purpose — This Clinical Research Center is dedicated to a multidisciplinary research program in the basic and clinical aspects of Otoneurology. The program is to be accomplished through a balanced endeavor of basic, developmental, and applied medical research.

The objective of the basic research program is the study of the function of the inner-ear receptor organs and central nervous system elements which, together, are responsible for the maintenance of equilibrium and hearing.

The clinical research program's objective is concerned with the diagnosis and treatment of disorders that cause deafness, tinnitus, vertigo, and dysequilibrium.

There is a broad representation of disciplines among the individual investigators covering medical and basic sciences pertinent to the study. The work is directed toward the application of modern technology to the development of new diagnostic methods and the acquisition of the fundamental information for the solution of otoneurologic problems.

Future Plans — One of the main goals of this project is the development of objective and reliable quantitative methods for the functional evaluation of the vestibular and auditory systems in normal subjects and in people with otoneurologic disorders. These new techniques are being developed from experiences obtained in basic science experiments. The proximity of laboratories and daily interdisciplinary cooperation make feasible the application of concepts and techniques developed through basic research.

Matching Speech to Residual Auditory Function (Human)

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Sponsor: National Institute of Neurological and Communicative Disorders and Stroke

Purpose — This research is directed toward improved signal-processing schemes to aid people with sensorineural hearing impairments. We intend either to develop improved schemes or to obtain a fundamental understanding of why such schemes cannot be developed. The proposed work includes study of linear amplification, amplitude compression, and frequency lowering. Also, attempts will be made to determine and understand the effects of variations in speech production on speech reception by impaired listeners.

The research on linear amplification is concerned with modelling the dependence of speech-reception performance on the speech materials, the background interference, the listener, and the linear amplification system. Initial work on this project involves an attempt to apply Articulation Theory to speech reception by impaired listeners.

The research on amplitude compression, directed towards listeners with reduced dynamic range, involves further study of multiband syllabic compression, as well as study of automatic volume control and limiting. The research on frequency lowering, directed towards listeners with poor hearing at high frequencies, continues to focus on pitch-invariant, nonuniform lowering. In both areas, the proposed work involves further exploration of the effects of various system parameters on speech-reception performance, testing of a wider variety of subjects, and attempts to determine the underlying causes of the results obtained.

The research on the effects of variations in speech production is motivated by our belief that there exist variations, both intersubject and intrasubject, that lead to substantially improved speech reception, and that an understanding of these variations and their effects will provide useful background for the development of improved signal-processing schemes. The proposed work in this area involves the development of speech materials uttered by different speakers under a variety of speaking conditions, the measurement of speech reception by impaired listeners using these materials under a variety of listening conditions, and the attempt to correlate the speech-reception results with properties of the acoustic waveforms.

Auditory Communication and Its Disorders

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Sponsor: National Institute of Neurological and Communicative Disorders and Stroke

Purpose — Proposed studies include: 1) monotic and dichotic identification and discrimination of speech-like and other complex auditory patterns, 2) objective tinnitus and evidence for auditory frequency analysis, 3) processes in vowel perception, 4) psychoacoustic measurements of chinchilla, 5) comparison of human and chinchilla processing of auditory signals, 6) structural, physiological, and psychoacoustic changes following prolonged and intermittent exposure to noise, 7) design goals and selection procedures for hearing aids, 8) processes in lipreading, 9) development of tests of language and of speech production for deaf children, 10) ipsilateral acoustic reflexes, and 11) refinement of brain-stem evoked-response audiometry.

Effects of Aging Upon Communication

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Sponsor: National Institute of Neurological and Communicative Disorders and Stroke

Purpose — This group of six projects will investigate otologic, epidemiologic, audiologic, neurophysiologic, morphologic, histochemical, and laryngologic aspects of age-related communication disorders, chiefly clinical presbycusis (hearing dysfunction in the elderly) and presbylaryngis (laryngeal dysfunction in old age). From this information we hope to better understand the pathophysiology of these disorders, develop a new diagnostic test, establish better-defined hypotheses for future studies, and, thus, add to our ability to prevent, modify, and eventually, treat age-related communication dysfunction.

The first two projects examine the epidemiology of clinical presbycusis and its possible relationship to cardiovascular disease by analyzing the extensive HANES I database (project one) and by studying the auditory function of the Framingham cohort (project two).

Project three will examine the validity and reliability of cochlear distortion-products as an objective test of cochlear dysfunction using noise-damaged cats and presbycusic baboons and humans.

Project four will study the electrophysiologic and morphologic changes in elderly baboons with auditory dysfunction (identified by electrocochleography and auditory brain-stem responses) compared to young and aged controls.

Project five will study the nerve conduction time, stimulus parameters, and strength of the glottic closure reflex as well as muscle tension properties and morphology in young and aged baboons in order to isolate the pathophysiologic changes responsible for aspiration in the elderly. Project six will examine changes in steroid receptors in brain and larynx as a function of age and sex in the baboon.

Clinical Research Center for Communication Disorders

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Sponsor: National Institute of Neurological and Communicative Disorders and Stroke

Purpose — A Clinical Research Center for Communication Disorders in Children will be established within the Department of Otorhinolaryngology at the Albert Einstein College of Medicine. The Clinical Research Center will be formed from members of the department and other individuals working with the department presently engaged in clinical investigations in the area of children's communicative disorders.

Each project examines a specific aspect of children's hearing loss and/or speech and language abnormalities. The overall purpose of the Center is to provide information to prevent, cure, or care for hearing loss and/or speech and language disorders in children.

The data collected will give information heretofore unavailable on: 1) the incidence and prevalence of hearing losses (mild to profound) in high-risk infants, including those from middle ear effusion (MEE) and the effect of hearing loss on speech and language for this high-risk group; 2) the correlation of behavioral and electrophysiological responses in infants; 3) the acoustic properties of the external ears of children from 0 to 6 years of age; 4) the effect of less-than-profound hearing loss on speech and language in 4- to 8-year-old children; and 5) the characteristics of cortical responses to speech in children with language deficits. The Clinical Research Center will provide clinical research training for students, residents, fellows, and junior faculty in Otorhinolaryngology.

High-Frequency Acoustics in the External Human Ear

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Sponsor: National Institute of Neurological and Communicative Disorders and Stroke

Purpose — Recent research pertaining 1) to high frequency audiometry up to 20 kHz, 2) to the measurement of in-the-ear pressures produced by hearing aids, and 3) to the research and diagnostic applications of so-called cochlear distortion products have necessitated accurate knowledge of the acoustic wave motion in the external meatus.

The acoustic wave motion within the external meatus is a function of frequency, of the size (length, cross-sectional shape) of the canal, of the physical properties

of the eardrum, of the eardrum inclination to the ear canal axis, of the location and size of the sound source, and of the size, shape, location, and acoustic impedance of the microphone to be used for the pressure measurement in the ear canal.

"Phase I" research is to collect a set of molds of the external meati and of the conchae of human cadavers in order to determine the range of sizes and shapes of the canals and conchae and the inclination of the eardrum relative to the ear canal axis. The physical dimensions and shapes of these earmolds will be measured in order to design some scaled models which have acoustically significant but yet realistic features. Initially, miniature microphones will be used to determine the acoustical significance or order of importance of each "feature," such as curvature of the canal, eccentricity of the cross-section, eardrum inclination relative to the canal axis, off-axis placement of the source, etc. Then, specific microphone designs will be tested which will either cause a minimum of interference with the sound pressure at the microphone's location and at the eardrum or cause a systematic predictable deviation from the true pressure so that a proper correction can be made. Such microphones might be of a segmented, annular type or of a multi-element circumferential type, for example. Theoretical models will be used as a guide for such microphone designs in terms of shapes and placement and for the prediction of sound pressures at the "eardrum."

The long-range goals for Phase II are to develop experimental and theoretical models for sound sources, microphones, and wave-propagation models in the external ear which extend to the high frequencies.

The goal of Phase III is to produce such instrumentation commercially.

Multimicrophone Monaural Aids for the Hearing Impaired Person

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Sponsor: National Institute of Neurological and Communicative Disorders and Stroke

Purpose — The ultimate goal of this research is the development of sensory aids which will sample the acoustic environment at more than one point in space (multimicrophone aids) to improve the ability of hearing impaired subjects to function more effectively in complex environments containing interference and reverberation.

The more immediate goal is to explore the potential of multimicrophone systems for monaural listening in such environments.

The results of this research, combined with research on binaural interaction in impaired listeners, will provide solid background for the development of multimicrophone aids to assist impaired listeners who have significant hearing in either one or two ears.

The proposed research, which draws heavily from previous work on both natural and artificial spatially diversified sensor systems (binaural hearing and antenna/signal-processing theory), is concerned primarily with reduction of interference and coding of spatially resolved information. The techniques considered for reducing interference include both linear and nonlinear processing, and both fixed and adaptive processing. The study of spatial coding, which is motivated by the need to monitor the general acoustic environment as well as to focus upon a particular source, is concerned with the extent to which signals that

are spatially resolved physically can be processed for monaural listening so that the resolution is preserved at the perceptual level.

Results on the reduction of interference should be applicable to cochlear implant aids and sensory substitution aids as well as conventional acoustic aids.

Rehabilitation Strategies for the Hearing Impaired Person

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Sponsor: National Institute of Communicative Disorders and Stroke

Purpose — Rehabilitation strategies for the hearing impaired person will be developed and evaluated. Strategies for speech and auditory training of hearing impaired children and speech-reading training of adults will be considered. The impact of tactile and visual sensory aids on learning rates will be investigated and new types of sensory aids will be developed, including a computer-simulated master hearing aid and an experimental visual speech display system.

Basis data on the effect of classroom acoustics (i.e., reverberation) on developmental speech discrimination in hearing impaired children will be measured and appropriate sensory aids developed to reduce the deleterious effects of reverberation.

Hearing Aid Characteristic Selection

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Sponsor: National Institute of Neurological and Communicative Disorders and Stroke

Purpose — The overall purposes of the proposed research are 1) to study how the characteristics of amplified speech signals affect the performance and satisfaction of hearing impaired persons and 2) to identify an adequate means to identify the characteristics an individual needs in order to obtain the most acceptable assistance possible. The two principal tools we will apply in these studies are subjective judgements and articulation theory.

Three different subjective methods will be used. A magnitude estimation-production method of evaluating speech intelligibility will be developed in order to produce band-importance (BI) functions for continuous discourse and sets of nonsense sentences. Magnitude estimations of quality and intelligibility will be evaluated for reliability and validity with respect to intelligibility in a format designed for clinical use. The third method is an adaptive paired comparison procedure designed to run with a high degree of efficiency under computer control.

The adaptive paired comparison will be used to 1) investigate the relative importance of the characteristics of hearing aid reproduced sound to the acceptability of a hearing aid where acceptability is defined as the best combination of intelligibility and pleasantness, and 2) evaluate the intelligibility and other judged characteristics of new hearing aids or hearing aid types using juries of normal hearing persons.

Articulation theory will be used in an investigation of the relationship between the functional characteristics of frequency-by-intensity regions of impaired auditory systems and the speech intelligibility provided by those regions. Also, the distribution of the proficiency factor (PF) will be measured in narrowly

defined linguistic groups. Finally, hearing aid performance will be evaluated using the concept of hearing aid efficiency in which frequency response and S/N ratio effects are "controlled" by the use of the articulation index. Standard and nonstandard measures of electroacoustic performance will be related to hearing aid efficiency.

Suprathreshold Auditory Behavior

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Sponsor: National Institute of Neurological and Communicative Disorders and Stroke

Purpose — The long-term purpose of this proposal is development of reliable procedures for evaluation of performance of a hearing aid on persons with sensorineural hearing loss. Specifically, studies are currently in progress to establish the effects of spectral shaping on speech recognition and the effects of background competition on speech recognition.

Development of a Cochlear Prosthesis

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Sponsor: National Institute of Neurological and Communicative Disorders and Stroke

Purpose — Electrical stimulation of the inner ear and eighth nerve of animals and humans is being done to explore the possibilities for a prosthesis for hearing in the totally deaf. Preliminary results from this project, and from others, indicate that such stimulations can provide environmentally useful sounds, even from fairly crude electrical devices.

The goal of this research is the application of sophisticated speech and electronics coding strategies towards improvement (via multichannel electrodes) of "artificial hearing" in those deaf persons who have defective sense organs but viable nerve fibers amenable to external electrical stimulation.

Hearing Aids and Rehabilitation for Hearing Loss

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Sponsor: National Institute of Neurological and Communicative Disorders and Stroke

Purpose — The research project is intended to apply and evaluate recent findings in individual and group aural rehabilitation methods and materials to the study of persons with profound postlingual hearing impairment, and to develop and evaluate new methods and materials for the same group.

The major study will compare the communicative skills of persons who have received a multichannel cochlear implant with the skills of the profoundly impaired who wear a hearing aid.

Other interwoven studies explore 1) an approach to lipreading instruction that is based on an observed compensatory relationship between auditory and visual recognition of consonants, 2) the application of programmed instruction to phoneme, word, and sentence recognition, 3) the question of whether sentences

are better learned through the combined auditory and visual modalities or through the auditory modality alone, 4) the success with which those with profound hearing impairment can learn to attach meaning to a continuously repeated message that is at first unintelligible to them, and 5) the application of the tracking technique to aural rehabilitation. Findings on a Hearing Performance Inventory and the MMPI scale also promise more information on this group of patients.

Development of a Digital Hearing Aid and Fitting Procedures

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The purpose of this project is to develop a digital hearing aid and a companion fitting procedure that will improve the precision and flexibility of fit that can be achieved with hearing aids. Towards this goal, special laboratory-based systems have been assembled to evaluate the overall concept. These systems include a digital hearing aid breadboard (DHAB) and a computer-based audiometer system. The system operates in real time and is better than most analog systems including hearing aids. The system is well suited for parametric studies of digital processing algorithms intended for hearing aid applications.

Progress — Application programs have been written for the DHAB to simulate, in real time, a four-channel instantaneous compression hearing aid. The input encoding can be changed from linear PCM to compounded PCM over different dynamic ranges to determine the effect of these signal processing parameters on the results of speech recognition experiments with hearing impaired subjects. In addition, programs have been written for the computer-based audiometer that measure the patient's residual hearing, that program the digital hearing aid, and that test the patient's ability to recognize sounds of speech. This allows us to evaluate the fitting procedure of tailoring the gain and maximum power output of the aid in a frequency-dependent way to conform to the patient's range of threshold, most comfortable listening level, and uncomfortable listening level.

Preliminary results with 12 patients indicate that the new testing procedures are accurate and efficient. More comprehensive testing will continue throughout this next year.

The preamplifier circuitry for the signal and probe microphones has been redesigned and fabricated on a tiny printed circuit board with surface-mount components. This new design, which fits easily into a behind-the-ear case and which connects to the in-the-ear transducer module, will be incorporated into the DHAB system in the near future.

Future Plans — Preliminary design of the wearable version of the digital hearing aid that will be fabricated during this next year is nearly finished. This design utilizes conventional parts and includes all of the features of the four-channel compression aid, including probe microphone reporting and communication with and control by the host computer of the audiometer during testing of patients. The wearable unit will be pocket sized and have a battery life of about 10 hours.

A preliminary study of the power consumption and size requirements of VLSI (very large scale integrated) circuitry suitable for hearing aid signal processing has been completed. Our study is based on a recent VLSI design project at Washington University in St. Louis. We examined this design assuming a feature size of 1-micrometer and a power supply of 1.5 volts. This structure is sufficiently complex for implementing the four-channel hearing aid algorithm and appears to satisfy the requirements of low power and small size.

Variables Affecting Hearing Aid Performance

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Hearing aid prescription and evaluation procedures rely either on direct or indirect estimates of sound pressure in the ear canal, or on behavioral comparisons of auditory performance. The overall objective of this program is to study variables which affect the data derived from those procedures.

The independent variables to be manipulated are: ear canal volume, ear canal static pressures, the acoustic stapedial reflex, ear pathology (both conductive and sensorineural), and transducer types. The dependent variables to be studied are: probe microphone measures of ear canal spectra, pure-tone threshold measures, and word recognition ability.

Progress — The work to date has focused on the development of a computerized (HP 1000F) system to acquire, store, and analyze ear canal spectra produced by a broad-band noise and to subsequently derive ear canal and eardrum impedance from measurements made at the driving point in the ear canal using a method similar to that described by W. Rabinowitz in 1981.

Data files have been structured to permit quick access to each of the records. Each record allows the storage and access of exact information about the nature and source of the record. Routines have been added to permit extraction of magnitude and phase data from the complex spectrum provided by a Bruel and Kjaer single-channel FFT analyzer. The programs implement conversion routines so that spectral and temporal waveforms can be stored and plotted in many forms. A three-dimensional plotting routine allows the analysis of the effects of static pressures on spectra and eardrum impedance.

Currently, statistical routines (correlation and descriptive statistics) are being tested. These routines allow selection of any set of records for analysis and comparison of one or more records to another record. Finally, a set of executive routines have been developed to allow the user to alter the flow of processing in a very flexible way. These routines also allow storage of the flow of procedures in a command (batch) file.

C. Speech Impairment

[See also pgs. 134, 135, 302, 360]

Tongue-Initiated Speech Prosthesis for the Laryngectomy

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Sponsor: VA Rehabilitation, Research and Development Service

Purpose — The major obstacle to the design and fabrication of a successful prosthesis for this purpose has been the inability to balance the power needed to produce recognizable speech against a secure anchor for the device. The result seems to be tissue deterioration at the anchor site whenever the power level has been adequate to produce speech. In addition, it has been extremely difficult to produce speech with any available prosthesis which did not make the patient at least somewhat self-conscious.

This project is attempting to determine the minimum frequency requirement needed to strike a balance between the quality of speech and the complexity of the prosthesis. This will require the support of the speech therapy community so that the needs of the patient can be accurately identified and addressed while, at the same time, isolating the fundamental components of each patient's speech pattern. If these components can be identified and duplicated adequately, it may be possible to provide patients with at least a partial replication of their speech pattern following surgery.

Efficacy of Remote Delivery of Aphasia Treatment by Tel-Communicology

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — There are many travel barriers that inhibit subjects with aphasia from receiving treatment. The remote location of speech-language pathology treatment centers often impedes continued treatment after the acute phase. Because of travel barriers, treatment programs may be based on factors other than the rehabilitative needs of the patient. Considering the large numbers of veterans with aphasia, results of this comparative study of TEL-C and clinic delivery systems for treatment of aphasic subjects should be of significance in the areas of service delivery and cost control.

The specific purpose of the project is to compare the efficacy of two methods of delivery of an aphasia treatment program: by 1) remote delivery of TEL-Communicology, involving both clinician and computer-assisted delivery, and 2) face-to-face delivery in the clinic.

The comparison of the achievement levels of subjects in each group is based on:

1) Pre-treatment, interim, and post-treatment evaluation of patient changes in communicative ability, and

2) statistical analyses of certain health care delivery criteria that measure availability, accessibility, acceptability, and cost-effectiveness.

The long-term objective of the project is to determine if TEL-Communicology is efficacious and cost-effective, and if it makes quality health care more available and more accessible.

Subject selection is based on criteria previously reported. Subjects meeting criteria are assigned to 1) a control group that receives 5 hours of face-to-face treatment, and 2) an experimental group that receives 5 hours of treatment by telephone. The same stimulus variables are used in both groups. The results of the pre-evaluation, interim, and post-treatment evaluations determine the rate and amount of improvement in each of the two groups.

During a 29-month period, 54 aphasic subjects have met criteria and entered the study. The charts of 4,120 neurologically impaired patients were reviewed. Of those, 2,980 patients were rejected because they were not aphasic. Of the patients diagnosed as aphasic, 522 were not accepted because of localization, 266 potential subjects were rejected because of etiology, and 94 did not meet the criteria of weeks post-onset. The remaining 258 were not accepted because they did not meet the criteria of age, PICA (Porch Index of Communicative Ability), visual acuity, or amount of previous treatment.

Birmingham serves as the project center of this 3-year project. The four Veterans Administration Medical Centers in New Orleans, Little Rock, Miami, and Birmingham serve as treatment centers. Birmingham VAMC is the project center.

Technical Aids for the Speech Impaired

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Purpose — The main objective for the project is the application of synthetic speech as an aid in communication and education. Several systems have been evaluated and the experiences have influenced further development. Two of the systems were built to fit on wheelchairs.

Progress — Further adaptation and field experiments are in progress. The development is oriented to reduce size and power requirements. The goal is a fully portable communication aid. Different methods to speed up communication rate are studied. New progress in the development of speech synthesis are promising in terms of naturalness and personal characteristics of the synthetic voice.

The KTH text-to-speech system has been augmented by Bliss-to-speech programs in Swedish, English, and French. Such a program translates a string of Blissymbols to a grammatically well-formed sentence. Blissymbols and typed-in text can be mixed for both spoken and typed output.

A lexicon gives the pronunciation and part-of-speech for each Blissymbol. This information is used in a deterministic, finite state, phrase-structure grammar. Within each phrase delineated by the grammar, the appropriate inflectional endings are added.

An electronic symbol board with 500 symbols has been developed so that a Bliss user can express himself by means of synthetic speech. Symbols are chosen with a magnet, and the device responds after an adjustable delay (the magnet can thus be moved over the surface of the board without unintentional symbol activation). A user can program the board himself according to his own individual symbol cards. Three sizes of cards are available: 2×2, 4×4, or 8×8 cm. The symbol board may also be coupled to other electronic devices (Bliss-TV, printer,

etc.), since both the connector and the symbol code follow the international standard (i.e., BLISSCII).

The symbol board can either be built as a special attachment to a text-to-speech system or with a built-in speech synthesis module.

Several Bliss-boards are currently being evaluated. A commercial version of the board is marketed by Rehabmodul AB, Vinterv. 41, S-171 35 Solna, tel. 08-7305125.

Experiments in schools have shown that, when using synthetic speech, the children become motivated, they develop their language, and get help in learning reading and writing. The speech-handicapped children seem to need such a support. A number of educational programs to train linguistic awareness has been developed in cooperation with Irene Dahl, a researcher in Umeå.

In a separate project, a new artificial larynx with intonation control is being developed.

Lexical Prediction for a Text-to-Speech System

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Purpose — It has frequently been stated that lack of speed is the major obstacle to technical aids for speech communication. With this need in mind, we have developed a lexical prediction system. An important application will be to aid motorically-handicapped users of our text-to-speech system to increase their typing speed.

Progress — We have developed a number of lexical data files (lexicons) and accompanying algorithms to predict words either from initial letters of a word or from previous words. Each entry in a lexicon of the 10,000 most frequent Swedish words has been marked for frequency and grammatical function. We are planning to develop our algorithm so that this frequency will be automatically adjusted and updated during use to allow the user to develop a personal frequency-weighted vocabulary. Since such a lexicon forms a separate module of the system, it is possible for one user to have several lexicons, one for each of various environments, or for several users to share one system.

These lexicons are accessed by an algorithm which, given an initial letter (or letters) by the user, predicts a word, making the prediction based on word frequency and a simple phrase structure grammar. Typing the first letter of a word results in accessing the most frequent word beginning with that letter from the First Choice Lexicon. Successive predictions are made from the Two-Letter Lexicon if predicted letters are overwritten by the user. If the first word of a two-word pair in the Two-Word Lexicon is typed (or accepted as predicted), the second word of the pair is automatically predicted without its initial letter being typed.

Preliminary tests are currently being carried out to assess the efficiency of the program. Using a 4500-word conversational text, data are being gathered concerning which words are predicted, partially or completely, and which lexicon they were retrieved from. Varying sizes and frequency assignment of the "current-topic" lexicon are being evaluated, taking into account how fast the lexicon is

filled, and how many times the words in it have been used. The phrase structure grammar is also being evaluated and modified.

Our next step will be to use a large amount of conversational data from various sources to test the final version of the program. Also, work has recently begun to develop a hardware version.

Development of a Procedure to Guide Prescription of Devices for Severely Speech Impaired Clients

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Sponsor: National Institute of Neurological and Communicative Disorders and Stroke; New England Medical Center Hospitals Biomedical Research Services Grant; Undergraduate Research Opportunities Program, MIT

Purpose — Research towards the development of a communication aid prescription guide is in progress at Tufts-New England Medical Center and Massachusetts Institute of Technology (under sub-contract to Tufts). The purpose of this work is to develop predictors of device-use performance. To the extent that the techniques developed prove to be valid, the procedure will permit performance predictions to be made about large numbers of devices with respect to each client—without actual device trials.

Progress — The patient-assessment procedure uses data from available sources (e.g., medical chart), from objective tests selected from published materials when available or developed within this project, and from clinician and client responses to questionnaires.

Motor assessment uses questionnaires and informal clinical evaluation to arrive at hypotheses as to which body parts and types of movement are most promising and should be examined further, using one or more of three objective protocols. Type 1 assessment looks at the dependence of performance in a reciprocal target tapping test on such variables as target width, inter-target distance, and direction of movement. The effects of key force and travel are in the process of being incorporated as variables in this protocol. Type 2 measures three quantities: switch closure time, closure to release time, and minimum time for a sequence of two closures. The third type of assessment looks at closure-to-closure time with pairs of switches mounted so as to be operable by different body parts.

A set of questionnaires for patient and familiar clinician are designed to elicit information about the patient's needs which will affect the usefulness of a communication device.

For device assessment, a protocol has been developed which specifies measures and measurement techniques to apply to devices. The protocol is intended to be exhaustive, i.e., all device information called for in the prescription process must be contained in the device file.

Development of parts of the motor assessment and some device measures is still in progress. Revisions of other portions of the assessment on the basis of pilot results with about 50 subjects (including 20 motor-disabled) are in progress.

In the area of prescription procedure, the products are a small number of indices which reflect the suitability of each device being considered for the patient. For example, one of the indices is "Maximum Motor-Determined (MDM) Rate," the best rate of communication the patient could expect, given his or her motor abilities and the device's characteristics. This score is obtained by

processing motor assessment data with each device's menu, layout, and geometry, by means of programs which, e.g., for Type 1, use the model of the patient's movement time in the reciprocal target tapping task to predict key-to-key time in the operation of planar keyboard devices.

Another score is "Benefit," the measure of the degree to which each device meets the needs of the patient (The mechanism for calculating B scores is an adaptation of the Lotus Spreadsheet). Presence and importance of needs are defined by formulas which evaluate the patient's and clinician's answers to the questionnaire on needs. Formulas applied to device data produce scores reflecting whether each potential need is met. The score for each need of the patient's which a device meets, times its importance weight, increments the B score for that device.

The third type of index, intended to reflect device learning-time demand as a function of user cognitive abilities, will not be available from the results of this project alone, since it will require collection of additional data.

Preliminary Results — Comparison of the measured communication rate of eight non-vocal keyboard-device users with their Type 1 reciprocal-tapping assessment data, revealed a correlation of $r = .865$ ($p = .003$). The results support the hypothesis that user motor abilities and the device menu, layout, and geometry are largely responsible for determining communication rate in the use of planar keyboard devices, and thus that this clinically feasible (1 to 2 hour) motor assessment procedure (Type 1) has predictive validity. Tests of the predictive validity of the other motor assessments, and of Benefit scoring, and collection of learning time data are in progress.

Experimental Analysis of Acquisition and Generalization of Syntax

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The purpose of Rehabilitation Research and Development Project #330 is to evaluate the effects of a syntax training program on the speech production skills of Broca's aphasic patients. Thus far, we have demonstrated experimentally controlled acquisition and generalization to non-trained members within response classes of the following sentence types: imperative transitives and intransitives, declarative transitives and intransitives, WH- and yes/no interogatives, comparatives and passives. Experimental control was demonstrated by employing a within-subject multiple baseline design across five sentence types. Multiple probes were incorporated into the design to pin-point the occurrence of experimentally controlled generalization. Rapid acquisition, with generalization within response classes, has been replicated across three subjects. Generalization to non-trained stimuli, to conversational speech, and to novel-setting conditions was limited in all subjects. Analysis of error responses revealed limited variation in response topography and restricted stimulus control of all trained forms.

Future Plans — Our plans are to modify our training procedures in such a way as to provide systematic variation of setting conditions, trainers, and stimuli, in an attempt to overcome restricted stimulus control and thus promote generalization responding in aphasic adults.

Computer-Aided Visual Communication for Severely Impaired Aphasic Persons

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Sponsor: VA Rehabilitation Research and Development Service; Neurology Service of the VA Medical Center, Palo Alto; Dept. of Neurology, Stanford U. Medical Center, and Stanford U. Academic Computing and Information Systems

Purpose — The overall objectives of this project are: 1) to develop a new type of communication aid—one which is matched to the needs of, and is operable by, chronic severely aphasic individuals; 2) to research the questions of device training and device use by severely aphasic users and their families; 3) to determine effective screening procedures, training regimens, support group activities and follow-up needs in connection with using this device; and 4) to make this device, together with training manuals and other support materials, available to speech therapists throughout the country for use by their severely aphasic patients and those around them.

Meeting these overall objectives will require achieving specific technical objectives in device design and construction. For example, our new communicative aid must be portable, and must incorporate the latest computer technology—powerful and advanced microprocessors, recently elaborated interface concepts, and the contemporary high-resolution graphic displays. Among its notable features are to be: 1) an interface incorporating a "mouse" pointing device, capable of being manipulated by one hand; 2) a visually based, iconic communication system displayed on a high-quality graphics screen; and 3) translation facilities, text displays, and voice output for communication with those unfamiliar with the system.

Our approach is to design a system—using contemporary technology—which takes advantage of the aphasic individual's residual strengths and abilities. Aphasia usually results from damage to the left hemisphere of the brain, which is where language processing takes place. It is often accompanied by a right hemiparesis, which leaves the subject with only his left hand fully functional. The earlier, unsuccessful aphasia rehabilitation attempts failed because, as a rule, they attempted to draw on natural language capabilities, which were destroyed and could not be restored. Our current system circumvents this problem, by emphasizing the subject's *visual processing*, which takes place in his brain's undamaged right side. Initial attempts at teaching aphasics this symbol language, using icons drawn on index cards, demonstrated the ability of many severely aphasic individuals to master the communication system.

The use of the computer provides many advantages. For instance, it enables us to animate symbols where appropriate. It allows us to check the user's communications for grammatical correctness, to provide prompts where desirable, and otherwise to assist the user in his construction and translation of communications. And it provides a powerful means to provide the user with a large vocabulary in a natural and intuitive way—via "explorable pictures."

Progress — Using an Apple Macintosh XL computer with a 5-megabyte hard disk, we have programmed a first version of our computer-aided communicative system. This implementation includes some, but not all, of the features described above. It does not yet contain either the "explorable pictures" mentioned above, or the ability to follow contexts, suggest prompts to the user, or otherwise actively assist in the construction of communications.

To test our concepts, we have trained two globally aphasic subjects in the use of

the card-based communication system, and have transferred one of these to using the computer-aided version. This subject has responded enthusiastically to the new system, and has shown significant improvement in his performance. We are now actively seeking additional subjects to train on the system.

This work has significance both for severely aphasic individuals and for researchers. For many in the chronic severely aphasic population, it holds out the hope for the first time of a return of simple functional communication, which could improve significantly the quality of their daily lives.

Portable Communication Aid with Synthetic Speech

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Sponsor: Rehabilitation and Development Center (Core Funding)

Purpose — Non-verbal communication aids that are easy to use, inexpensive, portable, and that produce voice and printed messages. Our ORATOR portable communicator combines all these features in a simple, cost-effective design. Messages are entered into ORATOR with an easily used keyboard. Each character is displayed as it is entered. When the message has been entered, the user can speak it, edit it, or save it for later use.

Prototypes of ORATOR are now available for consumer evaluation and market pre-testing. When we are satisfied that ORATOR does its job well, we will work with businesses to manufacture and distribute it.

The Comprehensive Communication System for Speech Impaired Persons

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The Comprehensive Communications System for Speech Impaired Persons evolved from a previous project published as the Electronic Communicator for Speech Impaired Persons. That previous unit utilized the Morse Code entered by joystick or other two-axis controller, and featured user-programmable messages, all in a portable microprocessor-based device.

The present system resulted from the field-testing of the previous unit which determined that the Morse Code system, while usable, required a definite training time for any speeds and was probably no longer necessary with the advancement of microprocessor technology. The new system, which implemented first on the Apple II family computer, uses a joystick to select letters directly. The letters are arranged in a square around the perimeter of the joystick with essential punctuation and a "shift" key for numbers and special functions. The system is easily learned, has capability for user-defined message strings, allows for printing or saving of text to diskette, and presents the letters in a large-type font for many who have visual perception involvement along with motor impairments.

The joystick is used to select each character the user wants to print on the screen. The standard joystick is bounded by a four-sided square. Starting at a predetermined corner of this square, the joystick slides in a clockwise direction along each side. As the joystick moves, its (X) and (Y) coordinates change. The program has a table written into it; as the coordinates of the joystick change, the program selects a corresponding character—a letter or number. That character is

displayed in the top-left-hand corner of the screen. It is two inches high (on a 12-inch monitor) and may be made larger or smaller as necessary.

When the user slides the joystick to a point where the required character is displayed in the top left corner of the screen, the user presses pushbutton one, (PB 1), on the joystick unit. That character then remains printed on the screen. The joystick is moved to select the next required character. This mode is called the Writing Mode of the program.

The present program is available on diskette and requires an Apple II family computer with 64K of memory and a joystick or other two-axis input device. A monitor and disk drive are also required.

Future Plans — are to reduce the system into a dedicated-microprocessor-based device utilizing the Intel 8748 microprocessor, a vacuum fluorescent display, EEPROM memory, and RS-232C serial interface as well as a special interface to the Apple II family keyboard input. This portable "Joywriter" as it is named, will permit the user to have a comprehensive communication system that is easily learned and that may be an independent portable device, and a keyboard emulator for the Apple II family computers.

Effects of Real-Time Biofeedback on Dysarthric Speech

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The purpose of this project is: 1) to investigate the effectiveness of computer controlled real-time high resolution color visual biofeedback in inducing mild to moderate changes in respiration and speech rate among dysarthric patients, and 2) to measure other speech parameters that may co-vary with change in speech rate and respiration.

Twelve cerebellar ataxic and 12 Parkinson subjects will be compared to normal control subjects during time-series experiments that induce change in respiration and speech rate. Measures of vocal fold movement, fundamental frequency, speech intensity, and speech intelligibility will be made in addition to the measures of speech rate and respiration. Simultaneous real-time extraction of all parameters except intelligibility and rate will be made by dedicated analog instruments connected to a laboratory computer. The computer will control the biofeedback display on the basis of the analog input.

Progress — Project personnel, all analog instrumentation, and most computer hardware have been acquired. Programs for data acquisition and calibration have been written. Validity studies regarding each measure are underway. Programs for data storage, analysis, and visual displays are being developed.

XIV. Head Trauma and Stroke

Motor Copy Procedures in Improving Function of the Upper Extremities of Stroke and Traumatic Head Injury Patients

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Sponsor: National Institute of Handicapped Research

Purpose — The approach investigated in this project relies upon muscle activity from the "uninvolved" side to serve as a template against which the patient could "match" muscle activity from the homologous-involved muscle or muscle group. Use of microprocessors with capabilities for storage of representatives of muscle activity from each arm is to enable patients to more effectively use bilateral descending motor systems in an integral part. This combination will result in a functional improvement that is cost effective and superior to existing therapeutic procedures. The patient can rely more upon his own neural substrates rather than the additional time consumption necessitated by constant interface with the clinician.

Progress — The first objective is to determine whether application of a motor copy technique can produce quantified improvement in an upper extremity function among target groups when members of these groups are interfaced to a commercially available device with capabilities for processing electromyographic activity.

This project randomly places patients in either the motor copy (experimental) or target muscle training (control) group. Each patient undergoes five baseline evaluations followed by 10 treatments to the involved shoulder region, and a similar number of treatments to the elbow and finally to the wrist and hand. Between each sequence of 10 treatment sessions, another evaluation is undertaken. Thereafter, follow-up evaluations occur at 3-month intervals. These evaluations consist of quantification of electromyographic activity and active range of motion for most muscle groups of the involved upper extremity. In addition, 21 functional tasks based upon time or force are assessed.

It is clear that of five patients in the experimental group and receiving treatment or in the follow-up phase to their baseline measures, all show slight improvement in range of motion, muscle activity, and function during acquisition of baseline data. During specific treatment of a limb segment, each of the five patients has shown appropriate changes in muscle activity and increases in active range of motion at each joint segment. Hyperactive muscles show reduced responses to stretch and increased activity during shortening while weak antagonist muscles have shown an increase in muscle activity. The most outstanding observation thus far is that treatment at one specific joint segment appears to cause a generalization of effect to those limb segments not as yet treated.

The second objective is to determine whether this motor copy approach is superior to a strategy enabling target group members to interact with the same commercial device by following recommended guidelines without using a motor copy technique.

Of eight patients receiving the motor copy procedure, all of the target muscle training participants showed some incremental performance during base-line measures. The small improvements occurred in the functional tasks as well as the electromyographic and active range of motion measures.

The third objective is to determine whether either approach leads to functional improvement generalizing from the limb segment under treatment to other limb segments or to the entire manipulative ability of the upper extremity.

Preliminary Results — A clear difference is beginning to emerge when the neuromuscular changes between the two groups are compared. Those individuals undergoing the experimental procedure appear to show a generalizing effect from specific treatment of one limb segment to the entire limb. Those patients in the target muscle (control) group show activity changes that are specific to the limb segment being treated—there is no generalizing effect. Individuals in both groups are showing improved manipulative ability (improvements in functional tasks). The magnitude of improvement and the speed with which such improvements occur between individuals in these two groups only can be ascertained as these sample sizes increase.

Patterns of Recovery in Traumatic Brain Injury and Stroke Patients in Two Different Service Systems

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Sponsor: National Institute of Handicapped Research

Purpose — Research has not yet clearly defined patterns of recovery in traumatically brain injured and stroke populations. Also not clearly defined are optimum therapeutic interventions and timing of these interventions for maximum functional outcomes. We propose to use departmental inpatient data and research data from current projects to assist in this documentation.

The objectives of this research are: 1) to chart recovery and plateau of function in all areas: cognition, motor, language, psychosocial, vocational; 2) to identify optimum times for therapeutic intervention; 3) to identify those variables that appear to predict potential and functional outcomes; 4) to delineate patterns of discharge status and identify reasons for discharge disposition; 5) to demonstrate the interrelationship of recovery and plateaus among the major indices of function; 6) to identify with VR personnel the timeliness, mode and consequences of VR intervention; and 7) to identify the fitness levels of traumatic brain injury and stroke, investigating implications for independent living and employment.

Progress — Achieving major objectives of this project is dependent upon data collected in research projects R2-R10, and the Department of Rehabilitation Medicine. Adaptation of PECS (Patient Evaluation Conference System) to the needs of the Department of Rehabilitation Medicine at the CRM has been completed and implemented. All departments requested some changes based on their experiences with this evaluation strategy. These changes included more specificity of some items, and additions and deletions of other items. These modifications were done within the general guidelines given by Dr. Richard Harvey, one of the developers of the instrument.

Future Plans — The work plan for the next year includes: 1) analysis and study of the data collected with the revised PECS form; 2) begin collating data relevant to recovery of function from other research projects which are now in the data collection stage; 3) begin work on the fitness index; 4) continue review of possible analytic approaches beyond descriptive statistics and initiate pilot testing of these methods with the data collected; and 5) continue review of the literature and contacts with other RTCs investigating the problems of the head injured and the stroke populations.

Spasticity Treatment and Motor Control: A Comprehensive Re-Examination

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Sponsor: National Institute of Handicapped Research

Purpose — Notwithstanding extensive research on spasticity, there have been very few studies directly comparing spasticity reducing treatments in the same patients or systematically exploring for subtle changes in motor control which may accompany reduced spasticity. This project compares the effects of several short-acting spasticity treatments (ice packs, antagonist vibration, benzocaine topical spray, drugs in single doses, or xylocaine motor point blocks) on spasticity and motor control in spastic hemiparetic victims of stroke or traumatic brain injury.

Passive arm motion is controlled by a modified Cybex Isokinetic Dynamometer so that spasticity is evoked by a controlled muscle stretch stimulus. The Cybex also provides resistance during tests of active motion. Spasticity and voluntary control of elbow and wrist flexors and extensors are quantified by means of integrated EMG from surface electrodes.

One goal of the project is to discover means by which physicians and therapists can identify those patients most likely to benefit from a combination of spasticity treatment and neuromuscular re-education, while avoiding unnecessary treatment in patients where reducing spasticity is not feasible or has no influence on elements of voluntary motor control. The project is in the early stages of data collection.

Retraining Proprioception Using Artificial Joint Angle Feedback and Stimulus Fading

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Sponsor: National Institute of Handicapped Research

Purpose — After stroke or traumatic brain injury, a persisting proprioceptive deficit may limit use of the affected arm even when recovery of motor control is sufficient for reach and grasp under visual guidance. In this project, an attempt is made to retrain proprioception using artificial joint angle feedback.

The patient practices limb positioning and the artificial feedback stimulus is gradually withdrawn (stimulus fading) to help the patient make an error-free transition to reliance on internal proprioceptive cues.

Preliminary Results — Results obtained thus far suggest that some proprioception-deficient patients can master the training task through a pure motor strategy, without improving in use of proprioceptive cues. These patients improve with

practice in active limb positioning accuracy, but when the limb is positioned passively, their ability to estimate its position does not improve. The feedback training task appears to benefit patients' ability to reliably produce extension or flexion movements as required, and perhaps to reduce involuntary drift when trying to hold one position.

Forced Use in Improving Function of Upper Extremities in Traumatic Head-Injured and Stroke Patients

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Sponsor: National Institute of Handicapped Research

Purpose — Most clinicians agree that a patient's inability to spontaneously or volitionally move a hemiparetic upper extremity during functional activity may be the result of a learned non-use of the affected extremity rather than specific motor deficits. This concern needs to be validated in a quantified manner. If, in fact, a patient has not learned to use an involved upper extremity, forcing him to activate that limb could result in learning functional consequences. The notion of forced use, therefore, may be a relatively simple yet effective vehicle to facilitate upper extremity function and ultimately maximal potential use of the involved arm and hand.

Progress — The first objective is to determine if forced use of the hemiparetic upper extremity results in a significant increase in patient self-reports of functional behavior.

At the present time, nine of the 16 patients being seen have completed the forced use interval and are in at least the 4-month follow-up phase. We have self-report scores on these patients taken for the week prior to the forced use interval, during the 2 weeks of forced use, and 1 week thereafter. Statistical analyses of these data will be done after all of our patients have completed their involvement in the forced use interval. A review of the numerical changes, however, clearly indicates that of the 17 tasks monitored in the home environment, an increased frequency of attempts for each of these tasks clearly occurs during the forced use 2-week period and is maintained during the 1 week following forced use. We believe that this tendency will continue to exist as all of our patients progress through the forced use interval.

The second objective is to determine if the forced use procedure improved the quality and speed of movement in a series of functional tasks.

Normal individuals showed comparatively consistent performance during each of the 4 weeks when their efforts were repeated. The magnitude of change in experimental subjects was substantially greater than in a normal subject sample and the amount of improvement appears to become greater for tasks that involve use of the entire limb rather than isolated segments (shoulder or elbow). These data will be subjected to statistical analyses after more patients have completed the forced use interval and more follow-up data are obtained. Nonetheless, a preliminary application of a multiple comparison test (Bonferroni Multiple T Test) suggests that significant improvement occurs for all tasks beginning during the forced use interval and, in many instances, continuing during the follow-up phases.

Rehabilitation of Cognitive Deficits with Interactive Computer Assistance

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Sponsor: National Institute of Handicapped Research

Purpose — Some of the most frequent sequelae of closed head injury are problems in attention, memory, visuospatial skills as well as planning and organizational skills. This project is developing a flexible and dynamic retraining system for the head-injured person, focusing on the deficit areas using a microcomputer as the therapeutic medium.

The objectives are as follows: 1) to design and develop cognitive rehabilitation procedures in attention, visuospatial skills, memory, and planning and organizational skills in microcomputer format; 2) to test and validate these procedures on groups of normals and head-injured patients; and 3) to disseminate these procedures to health professionals for use with their brain-injured clientele.

Progress — As of mid-April, the Attention Module had been debugged and its program code modified where necessary to correct any faulty functioning. A full programmer run-through was completed to ensure that each exercise in the module functioned correctly both independently and as part of the controlling framework, the master control program. Final adjustments were made to that part of the program which controls the videocassette recorder so that the audio instructions to the patients were correctly synchronized with the computerized exercises.

Future Plans — The remaining part of this quarter will be spent on author review. The author of the Attention Module will view the entire module and ensure that the program does indeed accomplish the goals delineated to the programmer.

There are four primary goals for the next quarter: 1) to complete the author review of the Attention module; 2) to modify the Attention Module as deemed necessary by the author from her review of the program; 3) to begin testing the Attention Module, both with an able-bodied group and with a group of head-injured patients; and 4) to design and structure the master control program for the Visuospatial Module and begin the programming for it.

The Relationship Between Cognitive Status, Objective Language Skills, and Functional Language During Recovery from Severe Head Injury

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Sponsor: National Institute of Handicapped Research

Purpose — Specific language deficits and motor speech impairments have been found to underlie many of the communication disorders which result from closed head injury. A review of the literature suggests that a better appreciation of the relationships between cognitive functioning and language usage, especially as they pertain to conversational competence, is necessary to fully characterize the nature of the communication disabilities of these patients. The impact of such findings provides strongly needed input into developing more effective treatment techniques for these problems. Based upon these needs, this project was developed to: 1) examine the clinicopathologic correlations among closed head injury patients distinguished by neurological variables (site of lesion, presence or absence of hematoma, duration of coma, etc.) and speech/language and

psychological test performance; 2) determine the relationship among objective speech/language and psychological test scores and measures of communication competence; 3) describe patterns of recovery in communication and thinking during the first 24 months after severe head injury; and 4) describe the long-term outcome of severe head injury on communication and thinking abilities.

In order to achieve these objectives, two groups of patients are being studied. A longitudinal group tested at 6, 12, and 18 months after injury and a long-term group at 24 months or greater after injury. These patients, aged 17 to 50 years, have a documented period of coma greater than 24 hours and a hospital admission, at least a seventh-grade education or evidence of ability to read and write, a history of employment, as well as no history of previous heavy use of alcohol or drugs, and no psychiatric hospital admissions. Restrictions in variables such as sex or race have been determined to be unnecessary. The test battery is composed of standardized speech/language and psychological tests. Videotaped conversational interactions provide the basis for gathering pragmatic data from observational techniques. The conversational samples are then analyzed by means of a protocol rating pragmatic behaviors which encompass verbal and non-verbal aspects of the patient's utterances, the formal linguistic parameters of the utterances with respect to meaning and context, and the success with which patients communicate their intentions by accepted standards of conversational interaction.

The project is in the data collection stage at the present time. Anticipated analyses, in addition to descriptive statistics, include repeated measure analyses of variance and multiple regression.

Future Plans — Future goals of the project include completion of data collection procedures, and subsequent data analysis. Results will be disseminated through appropriate publications and other training activities.

Social Skills Training as a Facilitator of Adjustment to Traumatic Head Injury

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Sponsor: National Institute of Handicapped Research

Purpose — Although medical advances have increased survival rates for closed head injury patients, existing interventions are insufficient in meeting their needs. Frequently, rehabilitation programs do not effectively address the documented interpersonal perception and social skills deficits which have been shown to hinder progress in the patient's rehabilitation. The long-term effects of such deficits include low rates of employability and increased social isolation. The proposed study will augment the rehabilitation process for closed head injury patients through the application of a social skills training package proven effective with other populations.

The objectives are to: 1) develop the Emory Rehabilitation Adjustment Scale (ERAS); 2) document component social skill deficits in CHI patients; and 3) perform and assess social skills training with six CHI patients.

The target groups are patients with closed head injuries and the expected outcome is 1) an effective measure of social adjustment; and 2) a program for remediating social skills deficits in CHI patients.

Progress — To supplement the original construct validity data on 50 outpatient CHI individuals, 3 residential treatment facilities (1 in Texas, 1 in Massachusetts, and 1 in New Hampshire) have committed themselves to collecting and providing validity data on approximately 60 CHI inpatients. An alternative Professionals' Form of the ERAS has been developed, and professionals' ratings of patients on the ERAS are being compared with team consensus judgments of adjustment as the criterion. The reliability of the ERAS will also be established with this sample. Forms and detailed instructions for administration have been mailed to the identified residential facilities.

Patients trained during the current grant period were selected based partially on the presence of social skills deficits documented by trained raters. The patients were observed in videotaped scenario enactments, as well as during unstructured free social interaction. Data obtained from family interviews, clinical observations, and ERAS ratings also were used for preliminary screening.

An additional four CHI patients have completed social skills training during this grant period, bringing the total to eight patients. There are two more patients than the six previously projected. Preliminary results based on "blind" ratings of the videotaped free interactions indicate significant training effects in each patient. Three of the four patients showed significant training effects in two or more of the target behaviors.

Nutritional Assessment of Closed Head Injury Patients (on Hold)

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Sponsor: National Institute of Handicapped Research

Purpose — The high incidence of malnutrition after closed head injury is currently unexplained. A large percentage of the patient population upon admission to the Rehabilitation Unit are determined to be in a severe state of malnutrition of an unknown cause. This is complicated by the need to increase the activity level, to recover from other injuries, and to learn new functional and cognitive skills. The severe degree of malnutrition in the Rehabilitation Program may impair physical recovery and cognitive recovery.

There is a need to learn the relationship between malnutrition and the degree of recovery in functional and cognitive skills. Since the expense of aggressive protein, calorie, or zinc nutrition is minimal, the benefit will be tremendous if this protocol is effective and improves cognitive and functional outcome.

The objectives are as follows: 1) to confirm, using direct calorimetry, the work of Haide showing an increased metabolic rate after head injury; 2) to better define the etiology of malnutrition after head injury; 3) to assess the effects of malnutrition on rehabilitation outcome measuring cognitive deficits, functional levels, medical complication rates and length of stay in an inpatient rehabilitation facility; 4) to develop an optimum clinical treatment protocol for protein calorie malnutrition in these patients; and 5) to conduct a double blind controlled trial of improved protein, calorie, nutritional status and assess its effectiveness in improving rehabilitation outcome.

Progress — A series of patients admitted to EUH Center for Rehabilitation Medicine with the diagnosis of closed head injury will comprise the sample of the

study. Subsequent postdischarge follow-up exams are scheduled to evaluate progress to 1-year postdischarge. The inpatients are divided into two groups: 1) malnourished; and 2) normally nourished. The malnourished group is then divided into two subgroups for treatment. One malnourished group receives the standard protocol of nutritional therapy and the second malnourished group receives a more intense therapy containing 1.5 caloric/cc of nutrients. Nutritional, functional, neuropsychological, and neurological status are measured regularly.

Increased Self-Control in Closed Head Injury Patterns in Multiple Environments with Family Intervention

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Sponsor: National Institute of Handicapped Research

Purpose — Patients who have suffered a closed head injury and the resulting multiple disabilities in the areas of social, cognitive, and emotional functioning often find treatment for these problems unavailable in their local community or inappropriate to the specific needs of the head-injured individual. Traditional psychotherapy is often financially inaccessible and also frequently inadequate in effectively treating head-injured patients. Indeed, the complexities of the individual and family problems attendant to the head-injured require an indepth evaluation of the home setting and an understanding of the patient's functioning outside the environment of the therapist's office. This research was designed to demonstrate that group intervention in a camping environment coupled with family intervention can be highly therapeutic and a cost effective method of treating selected head-injured patients. This process is given the name of "Therapeutic Camping."

The objectives of this process are: 1) to provide a therapeutic program which allows head-injured individuals to remediate functional deficits that have resulted in behavioral, social, cognitive, and vocational problems; 2) to enhance the generalization and maintenance of newly acquired skills by using a family intervention program consistent with those interventions performed in the therapeutic environment; 3) to identify the therapeutically effective components of the camping experience versus "therapeutic camping" through the use of a "within subjects" single case experimental design; and 4) to develop a model program that can be utilized by treatment facilities that work with head-injured persons.

Progress — Twelve male closed head injury patients were included in this research. They met the following criteria: 1) All were between 17 and 49 years of age; 2) All had at least 7 days coma duration; 3) All were at least 24 months postinjury; 4) All had behavioral problems that interfered with their ability to function at home as documented via family report and interpretation of the ERAS; and 5) All were not actively involved in another treatment program. Persons selected were placed in one of three groups of four members each. The study utilized a single case experimental design to evaluate the hypotheses.

Preliminary Results — The results of this research provide significant implications for the treatment and behavioral remediation of closed head injury patients.

The main conclusions are that the use of the camping setting in the treatment of head-injured men provides an environment whereby persons involved in the treatment of head-injured individuals can provide in-depth therapeutic interventions in a setting which offers a variety of situations analogous to numerous tasks encountered by the head-injured individual in his daily life. This format allows an adequate amount (2 weeks plus follow-up) of time for a change in some severe maladaptive behaviors to occur. The therapeutic camping setting with family intervention provides the head-injured individual with a means of generalizing the skills learned in the campsite to the home environment.

Future Plans — Additional research with this intervention approach is indicated and needed. The therapeutic camping format provides a reasonable and cost effective method in providing impactful group and individual therapy for head-injured persons and should be used as such. The implementation of an intensive family therapy component with group and individual therapy provided in the therapeutic camping setting is critical in order for generalization to occur and should be included in similar interventions.

A Program for the Cognitive Rehabilitation of the Head-Injured

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Sponsor: The Frances and Augustus Newman Foundation and Head Injury Recovery Trust

Purpose — Rehabilitation of the brain damaged patient needs a co-ordinated program of assessment and training. While physical disability is easily identified and retraining programs can be devised easily, cognitive dysfunction such as fatigability, impoverished memory, diminished concentration, poor motivation, and a slowness of both thought and action are not measured easily and the retraining programs are difficult to devise and implement. Furthermore, the pattern of deficit is patient- and injury-specific and no universal retraining program can be expected.

Progress — Since 1978, a clinical research program has been conducted to evaluate the recording of brain electrical activity in the form of event-related potentials (ERPs) can make to the assessment of the functional state of the individual patient. The procedures are of two types; 1) 15-channel recordings of long-latency or 'cognitive' ERPs are obtained while the subject is performing a task and, 2) specific sensory systems are investigated, using records for examples of occipital pattern reversal visual and brain stem auditory responses.

These measures have been shown to be sensitive to brain damage and can be used as an index of recovery. It is not surprising that the potentials are more seriously disturbed in severe head injury (more than 7 days post-traumatic amnesia, PTA) but even a mild head injury (PTA less than 1 day) can lead to a disturbance of brain patterns that lasts months or years. As the patient recovers, the patterns return to normal (even though the time scale can be several years).

This is based on microcomputers because of cost-effectiveness in terms of 1) unlimited hours of reasonably structured stimulation; 2) flexibility in devising programs for particular patient needs; 3) retraining being done in the home; and 4) the high motivation that computer-presented materials engender. To increase

the number of patients on the program, to maximize the efficacy of the retraining, and to allow the continuous monitoring of performance, we have installed a 'network' linking the patients' computers to a central one at the Institute.

The next phase of this program is to validate the use of the micro-processor retraining program using the neurophysiological measures together with neurological, neuropsychiatric, and neuropsychological assessments as indices of recovery in two groups of patients and controls. The first group comprises patients with recent head injury where the improvement by retraining is superimposed on natural recovery and a second group comprises patients with long standing damage where natural recovery has ceased.

Computer Program for Brain Injury Evaluation

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Sponsor: Commonwealth Department of Health

Purpose — This project is to develop and evaluate a computer program for assessment and retraining of verbal and visual short-term memory skills in brain-injured adults and post-C.V.A. patients. The computer program will be written according to our existing specifications. We will establish norms, reliability, and validity for the assessment component of the program and evaluate the effectiveness of the remedial component.

Efficacy of Computer-Assisted Rehabilitation of Brain Injuries

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Purpose — A number of disciplines such as Medicine, Neuropsychology, Audiology and Speech Pathology, as well as Occupational and Physical Therapy, have been involved in the remediation of problem sequelae of brain injury. Within the past several years, computers have been introduced as part of the rehabilitation process. However, despite a proliferation of computer-based "cognitive rehabilitation" clinics throughout the United States, which make offers of new hope to patients and their families concerning recovery from brain injury through microcomputer applications, as yet there are no controlled studies which show the effectiveness of these procedures. The present study will attempt to evaluate the outcome effectiveness of computer retraining through a controlled experimental study.

Subjects will consist of 60 inpatients referred from the Rehabilitation Medicine Service. In Experiment 1, 30 patients with right hemisphere CVA will be assigned randomly to either an experimental or control group, with 15 patients in each group. All subjects then will be evaluated by the Departments of Psychology and Occupational Therapy. Patients in the experimental group then will begin an 8-week computer retraining program, in addition to the traditional rehabilitation program. Subjects in the control group will enter the traditional rehabilitation program only. Computer retraining will consist of 2 hours per day of intervention with computer software for a total of 10 hours of cognitive retraining per week. Different software programs will be used each week, with each set of programs

targeted primarily to a specific deficit secondary to right hemisphere CVA. At the end of the 8-week retraining program, all patients will be reevaluated with the same assessments to measure improvement in target abilities. In addition, patients will be reevaluated in 3 months to assess changes in adaptive capabilities.

In Experiment 2, 30 patients with left hemisphere CVA will participate. This design is equivalent to Experiment 1, except that patients also will be evaluated by the Departments of Audiology and Speech Pathology, and computer retraining will focus on improvement of ability deficits characteristic of left hemisphere CVA. Again, patients will be reevaluated at the end of the eight-week retraining program and at a 3-month follow-up.

The following hypotheses will be tested: 1) patients who receive computer-based cognitive rehabilitation, in addition to traditional rehabilitation (experimental subjects) will show greater improvement on target deficits than patients who receive traditional rehabilitation alone (control subjects); and 2) experimental subjects will show greater improvement in activities of daily living and overall adaptive functioning than will control subjects, thus demonstrating greater generalization of skills beyond the clinic environment.

Family Factors and Work Adjustment of Handicapped Mexican American Disabled

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Sponsor: National Institute of Handicapped Research

Purpose — There exists a paucity of quality research describing unique Hispanic cultural factors—such as, machismo, la palabra, la familia, and overprotectiveness—which influence the vocational rehabilitation process. Over a 36-month period, this South Texas research project will describe unique patterns of Mexican American family interaction, Mexican American family member attitudes toward disability, and these family member attitudes toward rehabilitation resource utilization for bilingual, bicultural, vocationally-handicapped Mexican Americans with disabling conditions caused by stroke or brain trauma.

All handicapped individuals (potential subjects) will have been: 1) medically rehabilitated; 2) certified eligible for vocational rehabilitation services by the Texas Rehabilitation Commission; and 3) determined to be bilingual/bicultural prior to selection as a subject, with their family selected additionally as subjects. After 3 months of vocational rehabilitation services, data will be analyzed to identify culturally-relevant family predictors of the development of competencies which promote attainment of vocational potential and work adjustment. As a result, during Year 2 of the project, a culturally-sensitive *Family Interventions Manual for Handicapped Mexican Americans* will be developed for modifiable factors, based on social learning theory and principles of operant learning, which promote patterns of family interaction and/or attitudes that facilitate the maintenance or development of the previously identified work adjustment competencies.

Finally, during Year 3, the effectiveness of these interventions will be evaluated experimentally through implementation of the family interventions as a part of the Individualized Written Rehabilitation Plan with Mexican American families of vocationally handicapped, bilingual, bicultural Mexican Americans disabled by stroke or brain trauma. Once documented as effective, training in the Mexican

American family intervention model will be provided to counselors of the Texas Rehabilitation Commission. Additionally, microcomputer software will be developed for use in identifying family "risk" factors and for making culturally appropriate family intervention recommendations to be used in conjunction with the McCarron-Dial Work Evaluation System. The results of the research also will be disseminated regionally and nationally during each year of the project.

Studies of Spasticity in Brain Injury Patients

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Sponsor: National Institutes of Health

Purpose — Chronic electrical stimulation of the cerebellum has been performed to reduce spasticity in brain-damaged patients. The purpose of our proposed study is to investigate the physiology of spasticity and to evaluate the efficacy of electrical stimulation as a therapeutic procedure. We plan to define rigorously the elements of spasticity and evaluate motor control in cerebral palsy, spinal cord injury, and stroke patients. Tests of fine and gross motor control, simple tracking movements, and tests to elicit developmental reflexes, muscle rigidity, phasic stretch reflexes, and "long loop" late reflexes will be performed. The cerebellar implant patients also will be evaluated with these tests in our continuing double-blind studies.

We hope to relate the specific motor impairments in the patients with damage of the central nervous system to the underlying neurophysiological abnormalities. Furthermore, we hope to correlate any functional improvement which may occur with cerebellar stimulation to physiological changes.

Spasticity—Mechanisms and Quantification (Human)

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Sponsor: National Institutes of Health

Purpose — Mechanisms of muscular hypertonia and weakness in spastic limbs will be studied using spastic-hemiparetic adult human subjects. Hypertonia is known to result from an abnormally responsive stretch reflex. The question to be addressed is whether this stretch reflex abnormality arises simply because stretch reflex threshold is reduced (a consequence of increased motoneuronal excitability), whether the inherent stiffness of the reflex response also is abnormally augmented or whether both abnormalities coexist. This distinction is fundamental for understanding the neurophysiological bases of spasticity and for designing techniques allowing quantification of this disorder.

Stiffness of normal and spastic limbs will be compared at comparable initial force and joint angle using controlled variations in load force or in limb position as test perturbations. Should differences in stiffness emerge, the reflex contributions of Ia, II, and Ib afferents will be assessed. Mechanisms of weakness in spastic muscles will be studied focusing on contributions provided by anomalously low rates of motor unit discharge. Spectral analysis of surface EMG recordings will focus on differences in power at low frequencies, the portion of spectrum where rate contributions become evident. Recorded differences will be studied using single unit intramuscular recordings. The role of cutaneous and small

diameter afferents from muscle groups III and IV in mediating the disorganization of motor unit recruitment and rate modulation will be studied by comparing the reflex response of muscles to cutaneous nerve muscle stimulation on normal and spastic sides of the same hemiparetic-spastic subject.

The studies on limb stiffness may provide techniques useful for the quantification of the severity of spasticity. Such techniques are necessary for accurate assessment of the response to various therapies (pharmacologic, surgical, or physical) and for charting the natural history of neurologic illnesses producing spasticity. The studies on weakness may provide an assessment of the importance of segmental afferent imput in mediating the abnormal patterns of motor unit recruitment and rate modulation.

Computer-Assisted Neuropsychological Assessment

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — There is a rising demand for neuropsychological assessments because of an increasing recognition of the disabling effects of brain pathology, and because of the association of cognitive disabilities with age. With support from the VA's Rehabilitation Research and Development Service, we have been designing and planning the development of a microcomputer-based assessment system to: 1) present sophisticated automated tests; 2) make use of the results to guide the administration of further tests; and 3) develop an "expert system" to aid in the diagnosis of neuropsychologically impaired patients. Such a system would capitalize on advances in computer technology and artificial intelligence methods to significantly increase our capacity to diagnose and describe the disabling effects of brain injury. Finally, we propose to make use of a network of VA facilities to enable ongoing norming and validation of the proposed system.

Progress — To date, we have completed extensive reviews of the pertinent neuropsychological and cognitive literatures. We also have reviewed prior attempts at developing automated cognitive testing systems. The proposed system is designed to have the capacity for organic growth so it will be easy to modify or add tests as new knowledge about brain function is developed. It is an adaptive testing system wherein the difficulty of items is adjusted as a function of the patient's performance. The system will have two levels in respect to tasks: 1) a comprehensive set of already well validated tests which have available norms and which are already widely accepted by practicing neuropsychologists; and 2) a set of cognitive psychology tasks designed to uncover the specific performance underlying task failure. The pattern of test results will be analyzed by an "expert system" which will assist in forming a diagnosis.

Future Plans — In the next year, we propose to implement software development of the "front end" of the system (i.e., the testing component). This will consist of a task development and a task presentation component. The former will have subprograms that accept as input, pictures, text, speech and tones. It will have a way of specifying the parameters of each input presentation and of the associated response to be collected. The latter will consist of I/O primitives, a group of tasks,

and an outer shell program that would call and control the individual tasks. The I/O primitives will present auditory and visual stimuli, as well as read inputs via button press, touch screen, byte-pad, and voice key. Also included are procedures to read a real time clock. Following this initial phase, the development of the "expert system" component will proceed in concert with the validation and norming process. We anticipate experimental use of the testing system to begin within 18 months.

Establishment of a Central Nervous System Trauma Center

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Sponsor: National Institutes of Health

Purpose — The purpose of this project is to determine the cause of the decline in mortality from head injury observed during the last 2 years in San Diego County and to develop a comprehensive program for spinal cord injury patients to include acute care and rehabilitation. We also will continue to develop a head injury remediation center for San Diego County and participate in the multicenter collaborative trial of high dose barbiturate therapy for uncontrolled intracranial pressure. Finally, we will continue our clinical research on evoked responses and catecholamines in severely head-injured patients.

Establishment of a Central Nervous System Trauma Center

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Sponsor: National Institutes of Health

Purpose — Data collection for a multicenter randomized, controlled double-blind clinical trial of barbiturate coma in intractable hypertension began on October 1, 1982. A study designed to derive a profile of the traumatic spinal cord injured patient began on January 1, 1983. Neuropsychological and psychosocial data are being collected on mildly head-injured patients to study the cognitive impact and subsequent natural history of mild head injury in different populations. Studies being continued or completed include: 1) an analysis of cognitive outcome of severe and moderate head injury; 2) analysis to characterize demographic and clinical features; and 3) the studies of the features influencing the outcome.

Establishment of a Central Nervous System Trauma Center (Human)

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Sponsor: National Institutes of Health

Purpose — The major new objective is to conduct a collaborative, single-blind, randomized clinical trial evaluating the use of high-dose pentobarbital therapy for the control of elevated intracranial pressure in persons who have sustained significant and life threatening head injuries. If effective, significant reductions in head injury mortality and disability are expected. Continuing objectives include the evaluation of acute and rehabilitative care, research on neuropsychological consequences of mild head injury, improvement of community care for the spinal injured, and research on methods for the control and prevention of significant head/spinal injuries.

XV. Miscellaneous

Memory Remediation in Older Adults: A Computerized Interactive System

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Memory change is associated with the aging process, change not only seen in pathologies associated with aging (e.g., dementia), but also seen in normal aging. Memory failure is recognized by both researchers and by older adults themselves as one of the major psychological factors changing with adult age. Even though older adults report their memories to be worse than younger adults, the actual relationship between memory complaint and actual memory performance is small, typically showing a small correlation. Subjective reports of memory and cognitive ability made by the older adults often fail to reflect the actual capability of the older adult. This makes cognitive remediation difficult, except in extreme cases where cognitive deterioration is both generalized and severe (e.g., closed head injuries, dementia).

One possibility for the discrepancy between subjective report of memory deficits and actual memory performance is the assumption that memory skill is a generalized ability. Instead, it is most likely that changes with age are specific and very different for each individual older adult.

Memory assessment in clinical settings often involves global assessment batteries, tests deriving from the psychometric perspective that often have limited application when remediation is desired. Another serious drawback with most clinical memory assessment batteries is that they are not validated on everyday memory behaviors and problems. Of eight batteries most commonly used in clinical memory testing, none use everyday memory problems as criteria for validation. For remediation to be successful, however, testing and remediation techniques must address specific memory problems as they are identified by either the clinician or by the older adult him/or herself.

Progress — We will develop and test an interactive system (compatible with both microcomputers and the VAMC computer) that allows the patient/subject to practice and deal with specific memory skills rather than to deal with memory as a generalized activity. Specific skills will be identified and then trained or remediated. Furthermore, these skills will be relevant to the specific problems being experienced by older patient/subjects. Using the MUMPS language (currently being used at VAMC), another feature of the system will be the ability to store and use patient-relevant information as a component of the memory-skill training. For each patient/subject, a dataset of the older adult's own experiences will be stored and used in the memory training scheme.

During the pilot phase of this project, several memory skills will be identified for pilot use in two ways. Memory questionnaire data will be examined from normative studies existing in the literature. Second, skills will be identified through interviews and questionnaires with both patient/subjects and VA staff

working with older adults on a day-to-day basis. Computer programs will be developed using the MUMPS language that are designed to train the memory skills through interaction with the computer terminal. The interactive system will then be evaluated for the few skills to be used in the pilot phase of this project, both in terms of its validity of memory improvement and in terms of user compatability (user response).

The project team consists of a cognitive psychologist with extensive research experience in memory performance of older adults, a VA clinician with experience with geriatric medicine and the VA population, and a mathematician with expertise in computer systems design and programming.

A Life-Span Approach to Product Design and Development for the Aging Population

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — We hypothesize that technology developed through an interactive process and coupled with an approach to design and development based on a lifetime continuum will be appropriate to and accepted by the end-user population. This interactive process requires user involvement at all stages of the development cycle. It is believed that user-focused research will insure a well defined need statement, which is necessary to optimize the relationship between human and machine and will aid in the diffusion process.

The Interactive Evaluation Model is used to focus on a life-span approach to product design and development. The project seeks to: 1) involve student design engineers and older people in intergenerational needfinding and design; 2) provide students with a broader perspective to design and development; 3) develop methodologies to better educate engineering design students to meet the needs of older users; 4) develop a model from structuring communication between users and designers, 5) develop criteria for evaluation of marketed assistive devices; 6) provide feedback to manufacturers of assistive devices; 7) facilitate interaction between academia, industry, and government; and 8) identify new projects to benefit the aging through the application of microcomputer technology.

Progress — The VA RR&D and the Stanford University Mechanical Engineering Design Division collaborated on two student projects. Both were designed to highlight the needs of the elderly and to educate the students in a life-span approach to design. In one of the VA/Stanford projects, the interaction between academia, government, and industry was of primary concern. In the evaluation effort, retired professionals are involved in the identification of needs and definition of appropriate technology for their peers. A computer class at one of the local senior centers (average age of the programmers: 69) helped in the evaluation of commercial and homebrew robotics for home and health care. Other seniors served as advisors and community liaisons for a project in needfinding at Stanford. The results of this research were presented at the 30th Annual Meeting of the Western Gerontological Society in March of 1984. While formal research is not ongoing, staff members continue to interact with students in the classroom and on an individual project basis, and seniors continue in the evaluation effort.

Development of a Life Satisfaction Scale Applicable for People with Severe Disabilities

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Sponsor: National Institute of Handicapped Research

Purpose — This study seeks to develop a clinically useful questionnaire that will allow insight upon the adjustment process of people with various disabilities. Four different clinical populations will be used, including visually impaired adults from the Western Blind Rehabilitation Center, spinal cord injured adults from the Spinal Cord Injury unit, Palo Alto VAMC, patients from the Rehabilitation Medicine Department, Palo Alto VAMC, and a control population of members from a local Veterans of Foreign Wars chapter. The questionnaire's short, concise format will enable it to fit anywhere from an ongoing program evaluation, to an individual clinical assessment, to a diagnostic screening device, or as a central core to more specialized research. Also, the development of normative, reliability, and validity data on four distinctly different populations will allow statements concerning the intercorrelations of age, type of injury, activity level, support systems, coping mechanisms, and satisfaction of one's own quality of life.

The unique aspect of this study is the incorporation of the concept of the subjective appraisal of quality of life as a useful and important aspect of rehabilitation care. Use of this concept allows researchers and clinicians access to each person's perceptions of life satisfaction at various times of their lives, rather than viewing adjustment as a dichotomous variable that occurs sometime during the inpatient rehabilitation program. This will aid in a more comprehensive rehabilitation program as well as tailoring rehabilitation to each person's individual needs.

Progress — Data collection was completed for the pilot group of 30 veterans at the Western Blind Rehabilitation Center. The questionnaire was administered at intake, discharge, and 6 months following discharge. Only preliminary analysis of a few questions has been done to date; it indicated a high degree of satisfaction with the rehabilitation received.

On the basis of this pilot study, the questionnaire was revised somewhat and has been given to a large sample at the Western Blind Rehabilitation Center, as well as a small sample of veterans in the other two clinical settings—the Spinal Cord Injury unit and the Rehabilitation Medicine Department. Approximately 34 students at the Western Blind Rehabilitation Center have been administered the revised questionnaire all 3 times, and another 70 have been given the intake and discharge questionnaire and are awaiting the 6-month follow-up. All incoming students are routinely given the intake interview as part of their initial interview with the staff psychologist. At the Spinal Cord Injury unit, 23 interviews have been done with patients who are in for either initial general rehabilitation or for a second visit. One intake interview has been done at Rehabilitation Medicine. The appropriateness of the questionnaire for these additional settings is being assessed carefully, and plans are being developed for data storage, and for analyzing the pilot data and the data currently being collected.

It is expected that the results of this project will lead to changes in the clinical tests that are provided by psychologists and other psychosocial team members involved in rehabilitation. Clinicians and rehabilitation researchers will have a

more objective basis from which to identify who will be most likely to benefit from a variety of rehabilitation services, as well as what specific services should be offered to each individual person. In addition, clinicians will have a more objective basis in determining each individual's satisfaction with life at various points in time during their life, and be able to compare this level of satisfaction with other people of similar age and disabilities.

Minimizing Occupational Barriers for Physically Handicapped Farmers and Agricultural Workers

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Sponsor: Deere & Company and the National Institute for Handicapped Research

Purpose — The project is designed to assist agricultural producers with physical handicaps who desire to remain actively involved in their farm or ranch operation. Five basic objectives of the project are:

1) determine the proportion of active agricultural producers who have physical handicaps;

2) identify the types of physical handicaps which hinder active agricultural producers in completing essential work-related tasks;

3) evaluate essential operating and servicing procedures on modern agricultural equipment to identify design factors which reduce or contribute to the barriers facing agricultural producers with physical handicaps;

4) develop, identify, and compile practical alternative designs, modifications, and accessories to aid agricultural producers with physical handicaps in operating agricultural equipment and completing other farm-related tasks; and

5) establish a resource center to compile and distribute information to physically handicapped agricultural producers and their families in order to assist them in remaining productive in an agricultural setting.

Progress — Presently, the project is involved with the following activities.

1) Publishing the *Breaking New Ground Newsletter* on a quarterly basis. Designed specifically for agricultural producers with physical handicaps and rehabilitation professionals, the newsletter provides case histories; information on modifications for farm tools, equipment and facilities; descriptions of new products and resources; and a calendar of upcoming events.

2) Information and referral service in response to specific requests from agricultural producers.

3) Assistance with designing, organizing, and conducting workshops for producers and rehabilitation professionals. These are conducted on a regional or statewide basis.

4) Research, design, and construction of hand controls and tractor manlifts that provide the greatest versatility and control for operators at the least cost.

5) Evaluation of existing lifts, controls, and other modified farm equipment and buildings to determine effectiveness and insure safety.

6) Development of a comprehensive resource center containing information on modified farm tools, machinery, equipment, and buildings.

7) Assembly of a product information file on companies who manufacture equipment that can be utilized by producers with various disabilities.

Future Plans — Over the next several years the newsletter, workshops, and research will continue as resources become available. In addition, a series of audio-visual materials will be developed that will focus on problems such as: design and construction of manlifts for tractors and self-propelled harvesters; design and construction of modified controls for agricultural equipment; farm building accessibility; and adapted farm tools and accessories.

Extending the Management Control Project: Assessing Impact, Outcome, and Client Satisfaction

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Sponsor: National Institute of Handicapped Research

Progress — The Management Control Project has significantly improved eligibility decisions, understanding of client needs, and increased agency fiscal accountability in state vocational rehabilitation agencies that have implemented the Management Control System. This project is analyzing pre- and post-implementation data of the first three states to implement the Management Control System. This analysis may have implications and suggest trends for states presently implementing the system.

Specific areas which are being assessed are: 1) time in status for clients successfully and not successfully rehabilitated; 2) case service costs for successful and unsuccessful rehabilitation clients; 3) acceptance rates of clients; 4) success rates of clients; 5) severity of disability; 6) number of clients placed in competitive employment following rehabilitation; and 7) occupational categories of clients successfully rehabilitated.

How the Congenitally/Physically Deformed Learn to Be Independent

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Purpose — Existing information on survival, long-term management, and development of children born with open neural tube defects of the spine (spina bifida operta, meningomyelocele, myelodysplasia) is incomplete or becoming obsolete. We propose a multicenter data collection and analysis network to provide current information about survival rates and morbidity associated with modern medical and surgical care, therapy, and education of the child born with myelodysplasia. In years one through three, participating center staff will be trained to implement a comprehensive biomedical management protocol. Concurrently, a psychosocial protocol to assess community, family, and the myelodysplastic child will be developed and field-tested in Seattle. In year four, the psychosocial protocol would be transferred to participating centers and implemented parallel to the biomedical protocol. Years four and five will involve extensive evaluation and analysis. Approximately 4,000 patients will participate in four to five centers over the five years of this start-up phase.

This project will test multivariate hypotheses concerning:

1) Type, technique, and time of surgical repair of the lesion and cerebrospinal fluid shunt placement including coordination of back closure with caesarean-

section birth, scheduled because the fetus was diagnosed as having an open spine;

2) The relationship of type of ambulation to functional mobility as affected by biomedical, social, and educational variables;

3) The ability of an affected child to develop into an independent, socially adjusted, employable adult as related to age of learning independent self-care skills and socialization; and

4) Cost-effectiveness of medical and surgical care, therapy, and educational programs.

Rehabilitation International Study on Social Security Benefits for Disabled Persons

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Sponsor: U.S. Social Security Administration

Purpose — The contract was designed by the SSA Office of Disability in consultation with the SSA International Policy Staff.

In 1980 the US Congress ordered reviews of eligibility of the majority of people currently receiving work disability benefits from the SSA. The reviews were ordered because of federal investigations which suggested the possibility of wide-spread abuse of the benefit system. Since 1981 nearly 500,000 beneficiaries were advised that they no longer met the medical criteria for benefits. Of these, more than 200,000 people regained their benefits following appeals.

Due to numerous court cases and conflict concerning eligibility criteria, a moratorium has been called on reviews of eligibility of beneficiaries. The SSA is now developing new criteria to assess medical improvement of beneficiaries. The SSA is taking this opportunity to study all aspects of its work disability benefits system and one of the methods it has chosen is an international assessment of how similar systems work in other countries.

The countries to be studied are: Austria, Canada, the Federal Republic of Germany, Finland, Israel, the Netherlands, Sweden, and the United Kingdom.

Progress — The study will be carried out by investigators familiar with the system in each country. Rehabilitation International member organizations in each country have identified primary investigators and consultants to conduct the eight national studies. A sub-group of the investigators developed a questionnaire for the study. Each primary investigator is responsible for preparing a national monograph based on the data and information collected. A cross-national analysis will be prepared on the basis of the monographs.

The three major aspects of the systems to be studied are: 1) definitions of work disability used and how eligibility criteria determinations are carried out; 2) how continuing eligibility of beneficiaries is monitored and reviewed; and 3) methods of encouraging and facilitating the return to work of beneficiaries.

The major research tool of the project, a specially designed questionnaire is constructed to elicit information about the process, starting from the point of entry into the system and describing the various possibilities and procedures which may occur.

The U.S. Social Security Administration has also identified three areas for particularly close examination of the experience of other countries. They are: 1) the evaluation of pain, particularly in situations where the clinical evidence is not

supportive of the claim to disabling pain; 2) definitions and criteria used to evaluate mental illness and to predict recovery; and 3) criteria for cardiovascular and musculoskeletal impairments.

The main products of the study will be eight national monographs describing the various benefit systems and a cross-national research analysis based on the monographs. A small international working conference on the results of the study and areas showing promise for future research will be held in Washington, D.C. in March 1986.

Toward Better Methods of Nerve Repair and Evaluation

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — This study involves the parallel development of adjuncts to mechanical methods of reapproximating severed nerves and systems that permit more accurate evaluation of nerve lesions.

Progress — To date we have determined that several non-suture methods of nerve approximation permit regeneration equal to that obtained by the best suture repair methods in both rats and primates. Early, but incomplete, data indicate that agents which decrease the inflammatory response of injury permit greater numbers of axons to regenerate across a repair site. Present efforts involve investigation of such trophic factors as nerve growth factor and pulsed electromagnetic fields.

To better analyze a nerve lesion we have investigated the potential of measurements of the magnetic field that is associated with a passing wave of depolarization along a nerve to provide better information about the health and numbers of excited axons. We have demonstrated that the magnetic corollary of the compound action potential can give additional valuable information about the nerve. Ongoing studies include an analysis of the added delays at a repair site as a determinate in clinical decision making and the development of easy to use intraoperative recording systems.

Aesthesiometry in Screening and Prevention of Neurotrophic Ulcerations

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Sponsor: VA Rehabilitation Research and Development Center

Purpose — Development of neurotrophic ulceration in the diabetic patient leads to amputation of limb and disability of these patients. Currently most information and effort is directed at treatment of the already formed neurotrophic ulceration. Information is known on prevention, but effective methods for quantitating the overall status of the diabetic foot are lacking. New criteria are needed on the variables which cause ulcer formation. This study will focus on peripheral neuropathy and its relationship to the diabetic's loss of protective sensation leading to ulceration.

It is proposed that Semmes-Weinstein Aesthesiometry measuring cutaneous touch pressure sensation could be an effective, practical method for quantitating the extent of peripheral neuropathy in the lower extremity of diabetic patients. New criteria utilizing aesthesiometry can be established which can assist in the

diagnostic process to predict the relative risk of development of neuropathic foot ulceration in the diabetic population. This project will follow 100 diabetic patients divided into three risk groups of equal size: low, medium, and high on the basis of cutaneous touch sensation.

Progress — These patients will be followed with noninvasive screening tests three times annually, in addition to their regular routine foot care. This proposed project is a survey of a patient population, no alterations in patient treatment will be done. The screening tests will include cutaneous sensation testing, a photograph of the plantar surface of the foot to document lesions and foot structure, and completion of a history/physical questionnaire which will be used as a database. The database will be analyzed by Clinfo statistical packages on the station-wide PDP11-24 computer, especially noting changes in cutaneous touch sensation and occurrence of ulcerations. Data will be evaluated to determine if cutaneous sensation is an effective parameter for division of risk groups. Each risk group will be evaluated to determine what other variables cause differences within the group.

In addition to determining the efficacy of aesthesiometry in quantitating peripheral neuropathy, this analysis of the database will provide a clearer understanding of the variables of ulcer formation and their relation to peripheral neuropathy. Clinically, this information can be used to enable one to intervene with appropriate treatment or preventative measures to control or prevent occurrence of diabetic neurotrophic pedal ulceration.

Epidemiological Index of Disabled Pacific Basin Veterans

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — This project is aimed at developing a database on the disabilities of Pacific Basin Veterans (especially from Hawaii, Guam, and American Samoa). This extremely dispersed population often are hindered in getting adequate care for disabilities because of geographic location. In addition, a range of cross cultural issues must be recognized and addressed in dealing with disabled veterans in the Pacific Basin.

A number of variables are of concern to us. They include: 1) type of disability; 2) availability of care; 3) level of care; 4) impact on community adaptation; 5) ethnic meaning of disability; 6) quality of general health care management; and 7) relationships between aging and disability. We intend to develop a cooperative relationship with the University of Hawaii in pursuit of the above data. An important design consideration in developing the database is that it be capable of continuous updating.

The project has been proceeding in preliminary data gathering on multiple fronts: 1) panels of experts have been interviewed; 2) prior efforts at developing such a database have been reviewed and analyzed; 3) archival data, including census data, are being considered, and pilot interviews have been done. We presently plan a three-pronged approach. First, we will identify all currently known disabled veterans and sample them in order to conduct extensive interviews and evaluations. Second, we will develop case-finding methods to

enable us to find other veterans with disabilities and interview them. Finally, we will conduct a telephone survey of veterans to establish the rate and nature of disabilities in the veteran population.

Thermographic/Spectroscopic Comparison of Soaks, Exercise, and Trental® on Diabetic Feet

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The objective of this project is to delineate any thermographic or spectroscopic differences within the diabetic population that could be used to screen out patients "at risk" of ulceration.

Using liquid crystal thermography and magnetic resonance spectroscopy, this project will study vascular reactivity in skin and the level of ischemia in muscle in the face of various therapeutic maneuvers. This project will evaluate patients equally divided into four population groups. Each patient will be interviewed and a standard questionnaire, including pertinent medical history and physical examination of the foot will be completed. Based on this information, patients will be placed in one of four study groups: 1) non-diabetic controls; 2) diabetic patients with no prior history of foot ulceration; 3) diabetic patients with a prior history of foot ulceration but without active foot ulcers; and 4) diabetic patients with active foot ulceration. Thermographic evaluation of all patients will be completed before and following three different therapeutic maneuvers: 1) exercise; 2) uniform warming; and 3) an 8-week therapeutic trial of Trental®. Magnetic resonance spectroscopy will be completed on a smaller set of patients in a similar manner evaluating exercise and Trental.®

Using the Clinfo statistical package, the database will be analyzed to determine how one population differs from the other and how exercise, warming, and Trental® affect thermographic and spectroscopic patterns. This information will aid in the development of a prospective index in the assessment of the diabetic foot.

Computerized Treatment of Acquired Reading Disorders

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Normal reading is dependent upon the integrity of two routes or functional systems (the phonological route and the lexical route). Dysfunction of either route results in alexia. The objective of our project, "Computerized Treatment of Acquired Reading Disorders," is threefold: 1) to develop therapy tasks suitable to improve deficient reading strategies associated with the lexical route or the phonological route; 2) to develop computer programs for an interactive computer which would provide the patient with self-paced practice on the above tasks; and 3) to assess the efficacy of these treatments when presented via computer interaction.

We have completed development of the six alexia treatment tasks and are in the final stages of selecting appropriate stimuli. We have completed equipment acquisition and installation. The first version of the computer programs were completed and we are beginning a 6-month debugging process with patient usage.

Rehabilitation Electronic Access Project

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Sponsor: VA Rehabilitation Research and Development Service

Purpose—The rehabilitation community with its numerous members, their varied professions and abilities, and geographic dispersion has developed its own special needs and problems. For example, without continued communication, informationally isolated islands of community members can develop. As a result, research activities and funding are often duplicated, new techniques and devices are not widely disseminated, the experiences of members are not communicated, and users of aids do not have a voice in their own development.

Computer-based information systems such as NARIC and ABLEDATA have been developed to address users' need to acquire rehabilitation information. Although the data these systems provide are a potential source of solutions, its primary means of access requires personal possession of computer or terminal and modem equipment, knowledge of their use, and proficiency with the system's specific command language. The need for such devices and skills are major barriers preventing the widespread and effective use of these on-line resources.

Dissemination of users' information currently presents another significant problem. There is presently no way of efficiently communicating needs, solutions, and experienced-based information among the members of the rehabilitation community. An independent solution is often pursued despite the possible existence of a solution somewhere within the community—a duplication of effort.

An ideal solution to this situation is a mechanism that enables rehabilitation community members to make informed decisions based upon an enhanced ability to interact in an effective and synergistic manner. If methods existed that allow easy access to information, the barriers that distance, schedule, finances, ability, and possession of equipment impose would be reduced, permitting wider participation by all.

By employing new methods to increase interaction with computer-based information systems, several improvements in the rehabilitation process could follow. First, a greater subscribership would be fostered by the elimination of the requirement for the traditional means of electronic communication—the modem and CRT terminal. Portions of the rehabilitation community that were excluded from this type of participation due to the burden of acquiring this equipment, the inappropriateness of the display, and/or the effort in learning its use then would be able to engage in information exchange. Easier access to computer-based information systems could provide a wealth of opportunities to members of the rehabilitation community. Information on devices, job opportunities, travel, and resources could all be obtained if user-appropriate electronic interfaces were available. Access to, and the use of, information systems employing easy access schemes would permit many users to make educated decisions on issues that affect work, purchases, prescriptions, and achievement of life's goals.

Progress—The Palo Alto Veterans Administration Medical Center's RR&D Center and Western Blind Rehabilitation Center (WBRC) have cooperated on numerous projects during the past several years. These projects include the joint VA/Stanford project to develop a personal information system for the visually impaired. Preliminary work conducted at the RR&D Center has demonstrated the

feasibility of a universally accessible information system serving the rehabilitation community. The WBRC has operated the Electronic TeleCommunications, Education, Training, Evaluation, and Research Activity (ETCETERA) and, more recently, the Computer Training and Education Program (C-TEP), which provides a community locus for training and research on computer-based aids for the visually impaired. Other local resources, including the Sensory Aids Foundation, provide a vocational setting for the practical application of this training. While other systems such as Abledata, Special Net, Wellnet, and Handicapped Education Exchange offer information in computer form, they all require the use of a modem and terminal or computer. A system that requires no special equipment for access (other than a telephone) and provides interaction between users is easy to learn and use. It is equally suited for all those interested in rehabilitation issues who promote a significant improvement in information dissemination and informed decision-making.

A computer-based information system accessible by Touch-Tone and voice recognition input and machine-produced synthetic speech can be developed and employed within the local rehabilitation community to foster increased information exchange and consumer involvement. These alternate means of retrieving and entering computer-based rehabilitation information could be incorporated into both existing and future systems permitting more members of the rehabilitation community to participate in electronic information exchange.

The goal of this project is to design, develop, and evaluate mechanisms that permit universal access to computer-based information systems. Its potential beneficiaries are both agencies and individuals. Federal and private organizations such as the Veterans Administration (RRD and WBRC Centers) and Sensory Aids Foundation will be involved initially. Individual participants include those with disabilities, physicians, manufacturers, therapists, policy makers, employers, those seeking employment, educators, and senior citizens.

This project seeks to evaluate alternate methods of access to computer-based information systems. Voice output, Touch-Tone signalling, and voice input strategies all will be researched as substitutes for the terminal and modem. Several data retrieval dialog schemes will be designed and studied as well. Their successful implementation would provide an alternative to the varied computer command syntax that must be learned presently. This could lead to enhanced information exchange that would benefit all those concerned with rehabilitation.

To foster wider participation with computer-based information systems, this project also will focus on enhancing the system interface. Data selection methods other than system-specific computer command syntax will be explored. Mechanisms such as a personalized on-line electronic librarian could make the process of information exchange easier, more interesting, and motivating. If these improvements were designed into many systems, a common means of accessing information could emerge.

Some activity on this project has already begun. Several speech synthesizers have been acquired and their characteristics have been investigated. Programming has been started, resulting in a set of software modules that perform spoken file output, Touch-Tone encoding and decoding of letters, and telephone management functions. Microcomputer hardware systems have been surveyed for their suitability for this project and a database software search has begun.

IPA Radiology

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Sponsor: VA Medical Center, Little Rock, AR

Purpose — The purpose of this research is to investigate the feasibility of generating a three-dimensional model of the carotid artery from a limited number of views of the artery produced by digital angiography techniques. The model generated could be displayed and rotated in space so that the radiologist could better visualize any restrictions or occlusions that might be present. Such a technique is desirable because restrictions or occlusions are often not directly visible in the few views that are practical to make. The radiologist has no way of knowing beforehand which views will yield the most informative images of the artery and, thus, may not be able to identify the obstructions.

The research investigation is based on the principle that X-rays passing through a constant density medium will be absorbed at a rate that is proportional to the thickness of the medium, and on the assumption that the blood passing through the artery is nearly uniform in density. The investigation is divided into two parts: 1) image processing for the extraction of the artery thickness from the digital radiological image; and 2) the generation of an artery model from a limited number of radiographic views.

Progress — To create a controlled experiment for the image processing aspect, a glass model of an artery was created with restrictions and occlusions. This model was X-rayed with and without radiopaque dye, and the resulting images were stored on disk. The images were acquired using a Picker Digital Radiographic System and were generated from several look angles, with and without movement, and with and without background clutter. The images were processed using several techniques of image processing, including image averaging, image subtraction, and histogram modification. A careful investigation of these images is being conducted to determine if one can estimate the thickness of an artery along one of the ray traces accurately enough to generate a suitable model for meaningful radiographic analysis.

The graphic generation of the three-dimensional model of the carotid artery was pursued with simulated data to allow researchers to investigate the two aspects of the problem simultaneously and to help isolate the limiting factors of the proposed method. First, cross sections of a hypothetical diseased artery were drawn on drafting paper. These cross sections were then digitized with a Summagraphics Tablet. Measurements of the lengths of parallel rays passing through each cross section at several angles were recorded. These data points were then used to evaluate algorithms for reconstructing the cross sections using one or more views. Reconstructions of each cross section were compared with the originals on a ray-by-ray basis, on a unit cross section basis, and on a statistical basis. Three-dimensional shaded and colored models of the arteries, original and reconstructed, were generated and compared. Many algorithms were investigated and evaluated with respect to accuracy, noise immunity, and computational requirements.

Preliminary Results — The image processing portion of the research was hindered by the lack of a method of transferring digital image data between the Digital Radiographic System and the University's Image Processing Laboratory. Although the hardware and software exist to execute this transfer, they have not

been made available by the manufacturers of the Digital Radiographic System. The images processed, therefore, had to be recorded on film and then captured into the University of Arkansas' system with an imaging camera. This film step introduced a large amount of noise and reduced image data dramatically. Still, it appears that one can extract the data necessary for the reconstruction from the digital radiographic images.

The graphical reconstruction of the artery cross sections and the entire sample arteries was not successful for one or two views, as expected. The reconstructions were quite good for most cross sections using three views, but gave erroneous results in specific types of abnormalities. The reconstructions using four views resulted in very good approximations for the cross sections and the sample arteries for every case of shape and distortion investigated.

Future Plans — Future research will investigate the effect of noise and motion on the results. In addition, a method of automatically extracting the required data will be investigated.

Treatment of Peripheral Arteriosclerosis with Diadynamic Current

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Mehalla-Kubra, Egypt

Sponsor: Mohamed A.M.M. Atia

Purpose — Peripheral arteriosclerosis has many victims all over the world and the struggle against it must be a universal goal. A number of valuable agents are available that can be applied to specific areas without causing any undesirable side actions in the treatment of this condition. Properly applied, they are of more value than any medicinal agents in the treatment of uncomplicated arteriosclerosis.

Progress — Twenty patients with lower limb arteriosclerosis were selected for the study. The male to female ratio was four to one. The ages ranged from 45 to 69 years old and symptoms duration ranged from 1 to 8 months. The claudication distances ranged from 200 to 500 meters. A control normal individual walked 1500 meters without experiencing a calf pain.

Medium-sized electrodes were applied paravertebrally one over the other in the lumbar region with the negative electrode in the caudal position. The Diaphase Fixe current was used for 4 minutes. The sessions were given daily for eight consecutive days with a bearable intensity, followed by an eight-day interval and another course for 4-month treatment.

Preliminary Results — The pain was relieved in 16 patients receiving three to seven courses of treatment. Eight patients became able to walk 1500 meters without experiencing any pain in the calf muscles notwithstanding their original claudication distances. The remaining eight patients were classified as follows. The first patient's claudication distance improved from 300 meters to 1450 meters after treatment. The second patient's claudication distance improved from 300 to 1400 meters. The third patient's claudication distance improved from 250 to 1300 meters and the fourth patient's claudication distance improved from 320 to 1350 meters. Finally, the fifth patient's claudication distance improved from 250 to

1300 meters. Three patients with rest pain improved and their claudication distances became 1250, 1200, 1100 meters respectively. Three patients discontinued the treatment for special causes. One male patient (aged 69 years) with 4 months duration symptoms and a claudication distance of 240 meters showed no improvement, despite receiving seven courses of treatment.

Only in the first and second decades of this century, advanced medical and surgical procedures have been used. Although physical therapy is only part of the total management of the peripheral arteriosclerosis, it plays an important role. Very few references were found in the literatures concerning the use of the diadynamic current in the treatment of peripheral arteriosclerosis.

This work has shown that the diadynamic current is capable of increasing the circulation in the muscles and with prolonged treatment, a considerable significant improvement of the circulation can be achieved in the case of lower limb arteriosclerosis.

This current influences not only the superficial circulation but also circulation at a depth. The mechanism of this action is due to the sympathicus effect. Apart from the increase in the pain threshold and the muscular excitation threshold, there is also an increase in the threshold for sympathicus stimulation. The paravertebral application shows more importance to the sympathicus action than to the direct action on the vasomotor.

The results obtained in the treatment of lower limb arteriosclerosis by means of the diadynamic current are based on a number of different effects. First, there is the sympathicus action. Second, the analgesic action of this current deserves special attention since it is the cause of the subjective improvement frequently preceding the objective improvement in the case of severe arteriosclerosis where pain is felt even while resting. Also, rest pain does not indicate the presence of irreversible pathologic change as the three patients with rest pain showed improvement to a good degree. The patient who showed no improvement with seven courses of treatment might have an irreversible pathologic change.

As a whole, diadynamic current therapy may answer many questions regarding peripheral arteriosclerosis and can be able to influence it beneficially. Hence, diadynamic current therapy is a special consideration in the treatment of peripheral arteriosclerosis.

Serum Antimyelin Activity in Chronic Relapsing Experimental Allergic Encephalomyelitis

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Purpose — The purpose of this project is to investigate the role of circulating antibodies in an animal model of multiple sclerosis (MS). The steps involved are as follows: 1) reproducible induction of chronic relapsing experimental allergic encephalomyelitis (CR-EAE) in SJL/J mice; 2) pathological examination of animals at various stages of disease; 3) collection of serum samples at various stages of disease; 4) application of serum samples to slices of brain and spinal cord tissue grown in culture to look for effects on myelin; and 5) measurement of serum antibody levels to various myelin components. Significant progress has been made on the first three steps.

Progress — CR-EAE was induced in SJL/J mice by two different methods. Using the first method, 37 mice were inoculated with a homogenate of mouse spinal cord tissue. Thirty-six of the 37 mice developed an acute attack of neurologic dysfunction 2 to 4 weeks after inoculation, characterized primarily by hind limb weakness with or without forelimb weakness. This was followed by gradual improvement, leaving the animals with variable degrees of residual weakness. Twenty-nine of the mice have experienced a relapse of disease, similar to the acute attack, and 14 have had 2 or more relapses. The relapses generally occurred at 2- to 5-week intervals, and resulted in a gradual accumulation of permanent neurologic deficits. This clinical picture is consistent with that described by other researchers and has features in common with clinical profiles of patients with MS.

Preliminary Results — Preliminary pathological material is available on six of the mice inoculated with spinal cord tissue. Three mice died 33 to 35 days after inoculation, during the first relapse of the disease. Microscopic examination of the brain and spinal cord showed evidence of inflammation around blood vessels and in the nervous system myelin in all three animals. Three mice died or were sacrificed in the chronic phases of disease, at 91 to 96 days after inoculation. These animals showed less marked inflammation, which was primarily around blood vessels. Special stains for myelin damage are still being processed. Based on other pathological reports of mice with CR-EAE, it is expected that the degree of myelin damage will increase with duration of disease. The pathological features of CR-EAE are quite similar to what is seen in patients with MS.

A second method of producing CR-EAE in SJL/J mice was also used. Seventeen donor mice were inoculated with guinea pig myelin basic protein (MBP), an important protein component of myelin. Ten days later these mice were sacrificed and a suspension of lymph node cells was prepared from the donors. The lymph node cells were then cultured for 4 days in culture medium containing MBP. Eight normal mice were injected intravenously with these MBP-stimulated lymph node cells. Six of the eight mice received optimal injections. All six of the optimally injected mice developed an acute attack of disease 5 to 12 days after the injection, characterized by limb weakness with or without incoordination. Five mice developed a spontaneous relapse of disease, usually 4 to 5 weeks after the injection of cells. Four had two or more relapses at several week intervals. The animals were left with a progressively more severe neurologic deficit after each attack, again mimicking the clinical picture of MS.

This model of passively transferred CR-EAE is particularly useful because the confounding variable of exogenously introduced nervous system tissue is eliminated. Successful use of this model has been reported by only one other group of researchers thus far. Pathological material on the six mice that received injections of lymph node cells will be compared with the pathology on mice receiving injections of spinal cord tissue. In addition, approximately 15 to 20 more mice will be injected with MBP-stimulated lymph node cells for study of serum samples and pathological material.

A total of 227 serum samples have been collected from the mice, during both exacerbations and remissions of disease. One hundred and forty-one of the sera are from mice with CR-EAE due to injection of spinal cord tissue, and 51 sera are from mice to whom the disease was transferred by lymph node cells. In addition,

15 sera were collected from control mice and 20 sera from mice injected with MBP. The serum samples have been frozen and stored for future use.

Future Plans — The serum samples will be analyzed for antibodies in two different ways. First, antibody levels to myelin components will be measured by a technique known as the microtiter ELISA assay. Antibody levels to MBP will be measured initially. Depending on the results, antibody levels to galactocerebroside, a myelin lipid, also may be measured. The serum samples will be checked for anti-myelin activity by a second method. The sera will be applied to slices of brain or spinal cord grown in tissue culture. By this method, the presence of serum factors, such as antibodies, which damage myelin or interfere with myelin formation, can be evaluated microscopically. The results of the tissue culture studies and the ELISA assays should provide complementary information.

The results of this study will clarify the role of antibodies in CR-EAE, which may further our understanding of the mechanisms responsible for perpetuation of disease and production of clinical attacks in multiple sclerosis.

Evaluation of a Comprehensive Cardiac Rehabilitation Program: Treatment Effectiveness and Long-Term Programmatic Outcome

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The major project idea to be developed into a pre-proposal will be the controlled comparison of a comprehensive Cardiac Rehabilitation Program (CRP) with a more traditional, non-rehabilitation treatment program. The proposal will ideally investigate three major questions: 1) do patients in the program show better outcome (as measured on behavioral, psychological, medical tests; self reports; or recurrence rates) than patients not in the program?; 2) what components of the program are most important in determining positive treatment outcomes?; and 3) is it possible to identify potentially successful and unsuccessful participants early in the program?

Progress — Initial programmatic studies have demonstrated many positive effects for patients who regularly attended and completed a comprehensive cardiac rehabilitation program. These changes have included improved metabolic equivalents, oxygen consumption, NYS Heart Associations' Functional Classification of heart disease, more sustained and regular exercise, reported knowledge of heart disease, improved psychological functioning, and positive lifestyle modifications. Compliance with sustained treatment recommendations and continuation of improvements have not been determined yet through systematic evaluation. Given the available literature reporting on compliance with even the simplest of medical treatment recommendations, as many as 50 percent of the patients may become noncompliant. Thus, early identification of participants who are likely to be compliant or not may be helpful in ascertaining factors which are likely to enhance treatment.

This proposal would initiate the following investigation methodology: The first fifty patients or more, if completed within a 6-month period of time, will be evaluated with the Cardiac Rehabilitation Questionnaire Comprehensive and

medical protocol currently in use for the Cardiac Rehabilitation Program. At that point, subjects who, due to distance or other factors such as the limited accessibility to the program, were not referred for cardiac rehabilitation will be matched for inclusion in the study. Completion of the post treatment measures used to assess participants in the CRP will then be obtained, and all necessary medical tests conducted (ejection fractions, BP, heart-rate resting, VO2, metabolic rating of physical activity). Initial comparison across treatment and non-treatment groups then will be made to assess the benefit of program intervention. Comparison will be made of targeted behavioral, psychological, dietary, lifestyle, and physical changes for the specified follow-up period of time. The effects of treatment outcome will be measured through the expansion of current follow-up efforts within the program to include systematic 1-, 3-, 6-, 12-, 18-, and 24-month follow-up visits or contacts.

Preliminary Results — The CRP has already initiated program evaluation studies documenting desired changes across the time of intervention. Factors relating to successful compliance, sustained lifestyle change, and continued physical benefits have not yet been initiated. While present staffing and resources have allowed for these initial investigations to be made, further funding will be necessary to expand the program in the desired directions and to design a proposal which will yield reliable and valid information.

Future Plans — By five years, the successful completion of this proposal will have demonstrated through objective evaluation of treatment outcomes the efficacy of our present program, the means to complete this type of evaluation, as well as some of the determinants of successful treatment at the time of treatment onset.

Nerve Conduction Velocity Study of the Palmar Cutaneous Branch of the Median Nerve

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Sponsor: Rehabilitation Medicine Service, VAMC, Long Beach, CA

Purpose — It is well documented that the palmar cutaneous branch of the median nerve arises from the radial side of the main nerve about 2–5.5 cm proximal to radial styloid. The nerve innervates the skin of the thenar eminence. It may be involved in trauma at the wrist or transected accidentally during decompression for carpal tunnel syndrome or during surgery for ganglion removal or Volar synovectomy in that location. Neuroma formation also has been reported.

Electrophysiologic study of the nerve has not been reported so far. In order to make a precise diagnosis of pathologic involvement of the nerve, it is essential to establish normal conduction values of this nerve. This will confirm clinical diagnosis of neuropathy of the nerve. The data obtained in this study on normal subjects prove to be useful to diagnose its involvement. DISA neuromatic electromyograph available in the electrodiagnostic laboratory of Rehabilitation Medicine Service will be utilized for this project.

At least 25 individuals (50 nerves) consisting of healthy volunteers among VA employees who are 20 or more years of age will be randomly selected without regard to sex or race. A history of peripheral neuropathy, diabetes mellitus,

alcohol abuse, or any systemic or local disorders that are likely to affect the nerve will be excluded from the study. A brief sensory examination of the tested hand to make sure that there is no clinical neurologic abnormality of the nerve will be performed prior to the test. Only individuals with a normal index finger digital nerve latency will be included in the study.

These individuals will be told the objective of the study and a signed consent will be obtained. There is a noninvasive and routine testing procedure in our laboratory that may take less than 30 minutes for each person.

The subject will be tested in a supine position with the forearm and hand supine. The active (pick up) disc electrode will be placed over the center of thenar eminence with the reference electrode 3 cm distally. The ground electrode will be placed over the dorsum of the hand. The median nerve will be stimulated 10 cm proximal to the active electrode using a surface stimulator, and the best response will be recorded. The stimulating electrodes at the wrist will be rotated as necessary to minimize baseline distortion due to stimulus artifact. When in doubt, orthodromic response also will be obtained from the nerve. The mean distal latency, amplitudes of the evoked response, and the standard deviations will be established.

Serial Short Segment Stimulations (Inching) of Ulnar Nerve at the Elbow in Normal Subjects and in Neuropathy

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Sponsor: Rehabilitation Medicine Service, VAMC, Long Beach, CA

Purpose—Ulnar nerve compression across the elbow is a well recognized common clinical entity. The nerve is prone to compression either in the condylar groove or in the cubital tunnel as it runs between two heads of flexor carpi ulnaris. The exact incidence of these two lesions in ulnar neuropathy is not known. Precise localization of the lesion, which is essential for appropriate surgical management, can be done most accurately by short segment stimulation of the nerve across the elbow.

The primary objective of the study is to obtain normal configuration of motor and sensory responses by short segment stimulation along the course of the nerve for about 100 mm in normal subjects. Motor nerve conduction velocity of the nerve in the forearm, across the elbow, and in the arm will be obtained in the conventional way using surface electrodes. Also, similar studies will be done on patients referred to Rehabilitation Medicine Service Electrodiagnostic laboratory with possible neuropathy of the nerve across the elbow. We also will evaluate whether stimulation with a needle is useful to more clearly resolve entrapment of the nerve as it passes between the heads of the flexor carpi ulnaris. Special attention will be paid to delay in conduction, drop in amplitude, and changes in shape and area under the curve of the responses across the elbow.

This method will be performed on 50 nerves in 25 normal volunteers who are 20 or more years of age selected without regard to sex or race. Subjects with symptoms or neurologic findings on examination for sensory changes and motor weakness in the ulnar nerve distribution will be disqualified. Persons with a history of alcohol abuse within the last 6 months also will be excluded from the study. Patients will be selected from those referred to Rehabilitation Medicine Service for electrodiagnostic testing. Electromyography of the ulnar nerve innervated muscles will be done to detect evidence of axonal loss in the nerve.

Patients with a history of bleeding tendency or an anticoagulant will not have electromyography. Patients with a definite history of ulnar neuropathy also will be studied to exclude the coexistence of: 1) motor radiculopathy of C_8T_1 roots in the extremity; 2) peripheral neuropathy; and 3) entrapment of ulnar nerve at the wrist or of other nerves at different locations.

This is a collaborative project with neurosurgery. The neurosurgeons will help locate patients for this study, provide operative reports of those patients who come to surgery, and help with postoperative follow-up. Individuals selected for the study will be told the objective of the study and a signed consent obtained.

Job Club

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Sponsor: National Institute of Handicapped Research

Purpose — The Brentwood Job Club has been developed under a basic skill building and self-help framework to help persons with chronic psychiatric disabilities gain employment. Unlike traditional job placement programs that rely upon vocational rehabilitation counselors to find jobs for their clients, the present program was designed to teach participants how to find their own jobs and then motivate them to persist in the job-seeking process. This approach not only uses available staff time more effectively, but also provides the participants with important job-finding skills that they are likely to need again in the future. Previous reports of Job Clubs among other populations have been notably successful, although this approach had not been reported among psychiatrically-disabled people prior to the inception of this project.

The purpose of the present project was to determine if the Job Club approach could be adapted to the specific needs of psychiatric patients and if such an approach could improve employment for this population.

Progress — Data have been collected on 170 psychiatric participants focusing on client characteristics, employment outcome, and 6-month follow-up outcomes. Data analyses have focused on identifying relationships between the clients' ability to locate and maintain employment as well as the impact of the Job Club program and other variables such as demographic information, work history, psychiatric history, and current symptomatology.

Preliminary Results — While the literature indicates that only 20 percent of psychiatric patients obtain jobs subsequent to hospitalization, over 65 percent of patients at Brentwood VA obtained employment through the Job Club. Results revealed that program intervention is the most significant factor in facilitating employment outcome with other demographic, psychiatric, and work history variables having statistically negligible effects on employment outcomes. However, the severity of psychiatric symptoms did predict those patients who were returned to their ward treatment program prior to completing the first week of the Job Club curriculum. These findings are seen as supporting the importance of a structured, behaviorally-based psychosocial intervention in vocational rehabilitation of severely disordered psychiatric patients.

While this program offers promise in reversing the vocational misfortunes of chronic psychiatric patients, more information is needed regarding overall efficacy and generalizability across the varied needs of chronic psychiatric patients. Although a significant number of patients secured employment through the Job Club program, half of them became unemployed within the first year. Hence, job placement does not secure job tenure.

Future Plans—Future plans will address these issues through: 1) a programmatic evaluation of the Brentwood Job Finding Club with a broad spectrum of psychiatric patients; 2) a controlled investigation of the contribution of proactive job maintenance training in helping patients keep their jobs; and 3) the controlled dissemination of the overall project to other sites across the country that serve specialized psychiatric patient populations.

Patients will be recruited from four different settings representing a broad program of chronic psychiatric disorders and levels of functioning. Each participant will complete a thorough vocational, psychiatric, and social assessment prior to beginning the program and data will be maintained on individual participation and outcome while in the program. Results will be evaluated through a series of multivariate analyses, controlling for vocational skills, psychiatric status, and program participation and be compared against selected reference groups.

All individuals will have monthly follow-ups for 1 year upon leaving the Job Club. Those who leave the program employed will be randomly divided into two groups to assess the efficacy of job maintenance programming in helping employed patients keep their jobs. Individuals assigned to the treatment group will participate in a behaviorally-based job maintenance program that teaches individualized skills designed to help them meet job-related problems and remain employed. Participants in the comparison group will receive no training.

Finally, the validated job-finding club and job maintenance training programs will be disseminated via controlled field tests to selected sites across the country to determine the general ability of noted findings. Special emphasis will be made to include sites that represent the special needs of psychiatrically disabled persons including the homeless, those within the criminal justice system, as well as those from rural and urban populations. Upon completion of the field tests, the validated program will be disseminated nationally.

Stimulation of Industry and Evaluation of Technology

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Purpose—Southwest Research Institute has initiated a Rehabilitation Engineering Center program focusing on "Stimulation of Industry and Evaluation of Technology." At the same time, a complementary Rehabilitation Engineering Center (REC) program was implemented at the Electronic Industries Foundation (EIF). The mission of these centers is to develop strategies and techniques for enhancing commercialization of a broad array of product types with an emphasis on devising, especially for the end-marketer, factual information about new applications of technology. The RECs solicit products to be used as experimental

models for the development of recommended practices. Most laboratory, user-trial, and limited clinical evaluations are conducted or managed by the Southwest Research Institute (SwRI) REC. Requirements of the cognizant regulatory agencies are studied, and evaluations are designed to assure acceptability. The EIF REC is responsible for linking the developer with potential manufacturers, investigating financial impediments, and planning marketing strategies.

Progress — The Rehabilitation Engineering Center has completed its pilot evaluation using the Storable Crutch developed through the Stanford Children's Hospital REC program. Initially, a pre-check safety and reliability analysis was performed. An engineering test and evaluation checklist encompassing criteria for human factors, strength, durability, and failure analysis was developed. Clinical evaluations then were performed through the University of Texas Health Science Center and the Audie L. Murphy VA Hospital. Concurrently, an engineering data package was developed from the prototype hardware to provide fabrication requirement information to possible manufacturers. Potentially-interested manufacturers were identified and put into direct contact with the crutch developer.

The Center also has participated in a round-robin laboratory test of manual wheelchair load-bearing ability. The full testing sequence of ISO static loading tests was performed in support of the RESNA-ANSI TAG effort at revising document DIS/7176/11. Managed by the FDA-Division of Medical Engineering, tests were conducted by SwRI, the VA Prosthetics Center, FDA laboratories, and Everest-Jennings, Inc. Test preparation required fabrication of specialized loading fixtures including a 100 kg test "dummy." All tests were conducted in a stress analysis laboratory according to the prescribed procedures. No permanent dimensional changes were recorded. Test results and recommendations were reported to the RESNA Wheelchair Standards Committee and the ISO.

Developed through the REC program at the Rehabilitation Institute in Ljubljana, Yugoslavia, the Vagicon X utilizes functional electrical stimulation to assist in controlling urinary incontinence in females. The Center staff has coordinated and participated in an engineering evaluation of this device, including laboratory analyses of materials, circuitry, and electronic function. An engineering acceptance and test procedure has been developed in preparation for formal clinical studies to be conducted in the United States.

The Center also focuses efforts on disseminating information related to evaluation activities and rehabilitation technology. The *TechEval* publication was developed to announce and report relevant instructional information. Additionally, the staff has made presentations at numerous conferences and workshops. Highlights include the development of an instructional course to enhance communication between rehabilitation device developers and product manufacturers and the presentation of workshop sessions addressing effective selection and utilization of technical devices. Articles were submitted for publication to various periodicals, exhibit booths were prepared, evaluation resources and manufacturers were visited, and responses to numerous information requests were processed.

Very few "standards" exist that apply to the evaluation of rehabilitation products. Consequently, the REC staff has supported the process of "consensus standardization" of performance criteria by actively participating in the RESNA

Subcommittee on Wheelchair Standards Development and the SAE Subcommittee on Adaptive (Automotive) Devices.

Future Plans — During the current performance period, the Center is planning to work cooperatively with the EIF/REC and other evaluation resources to produce a few, thoroughly documented, case studies of the combined evaluation/commercialization process that has evolved to this point. Efforts to develop and refine evaluation procedures will continue. The Center also will work toward attracting commercial and non-governmental support for evaluation service.

Predictive Criteria in Rehabilitation of ESRD Patients

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Progress — Evaluation of outcomes associated with dialysis patients' participation in a low-risk exercise program has been completed. Cybex assessments have indicated increases in muscle endurance in participants, and the data suggested a decrease in systolic blood pressure and an increase in hematocrit. Positive psychological changes included decreased depression and anxiety levels, increased feelings of control over own health status, and a general increase in life-satisfaction. The exercise program consisted of treadmill walking and riding an exercycle twice a week for approximately 40 minutes, plus encouragement to engage in brisk walking for 20 minutes three or more times a week.

Longitudinal assessment of medical, psychosocial, and vocational status of 150 ESRD patients first evaluated 1978-80, with two follow-up assessments at 18-month intervals, focused particularly on the effects of treatment changes.

Hypertension knowledge and treatment prior to renal failure of a stratified random sample of black dialysis patients and white dialysis patients were compared.

Attitudes toward, and experiences with, kidney transplantation among a stratified random sample of black dialysis patients and white dialysis patients were compared as well.

A survey of American Nephrology Nurse Association members was made to determine nurses' needs for additional training to facilitate patient rehabilitation. In addition, another survey contained reports from all hospital and clinic dialysis providers in the United States to determine the availability and nature of rehabilitation services.

Laryngeal Function in Normal and Abnormal Speech (Human)

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Sponsor: National Institutes of Health

Purpose — We are investigating the larynx centers on their control and role as a source function for speech. The research method aims at revealing the relationship between the controlling muscular and aerodynamic forces, the resulting configurational and vibratory adjustments, and the final acoustic output. Muscular activity will be studied by electromyographic techniques. Plethysmorgraphy will be used for estimating lung volume. Aerodynamic data will

consist of sub- and supra-glottal pressure and flow measurements. Aspects of laryngeal configuration will be examined by comparing data from fiberoptic images, high-speed movies, glottal transillumination, and electroglottography. Acoustic measures will include use of inverse filtering. A practical goal of many of the comparative measurements is to develop noninvasive methods of assessing laryngeal function that can be used to replace more direct, but necessarily invasive techniques.

An understanding of speech function requires an understanding of glottal abduction and adduction, the control of fundamental frequency, and the control of glottal configuration, because these area fundamental parameters govern segmental manner distinctions, suprasegmental control, and voice quality control. As part of this general account, the larynx-vocal tract interaction is examined from two points of view—first, temporally in segmental articulation, and second, aerodynamically and mechanically as they interact in FO and voice quality control.

Studies on normal speakers are to be paralleled by studies of three clinical populations: the deaf, the fluent and dysfluent aphasics, and the stutterers. The object of these studies is to provide information about mechanisms that may prove useful in remediative therapy.

Gas Flux Through Human Skin: Effect of Temperature, Stripping, and Inspired Tension

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Sponsor: National Heart, Lung, and Blood Institute of the National Institutes of Health and Ben Franklin Partnership Program of the Commonwealth of Pennsylvania

Purpose — The transcutaneous monitoring of PO_2 is a technique that has gained much popularity in the last decade. It has fulfilled the greatest need in the intensive care setting, especially neonatal intensive care. The technique has also been extended to such diverse areas as fetal monitoring, exercise physiology studies and stress testing, assessment of skin flap graft viability, and cardiovascular/pulmonary drug evaluation. The devices have demonstrated their greatest utility as trend monitors, and are especially useful as monitors of peripheral oxygen delivery. As a noninvasive monitor of arterial PO_2, $tcPO_2$ has been less successful. The correlation between arterial blood gas values and $tcPO_2$ has been good under stable and controlled conditions, but not entirely satisfactory, especially in adults in the clinical setting.

We sought to test experimentally the hypothesis that markedly increased skin O_2 flux at high temperature is due to arteriolization. We developed a mass spectral technique for examining simultaneous flux of H_3 and O_2 through intact adult human skin; the monitoring of H_e flux was used as an indicator for local perfusional changes. We have interpreted the data in terms of a simple model for O_2 and H_e flux that incorporates perfusional and diffusional resistances.

Progress — The flux of helium and oxygen through intact adult human skin was measured at various inspired concentrations and skin temperatures. The skin surface was then stripped with cellophane tape to alter the diffusional conductance of the stratum corneum. Helium flux for stripped skin was used to estimate skin perfusion as a function of local temperature, and diffusional conductance for oxygen was estimated from oxygen flux and perfusion. The flux of helium or

oxygen at constant skin temperature was related to inspired concentration by a simple linear model. Increasing surface temperature in the range 33-43°C produced a much larger increase in oxygen flux than in helium flux for intact skin. Skin stripping greatly increased skin oxygen flux. Estimated skin conductance for oxygen showed a more marked temperature dependence than estimated skin perfusion.

The results suggest that raising skin temperature in the range 38-43°C has only a modest effect on skin perfusion, and that stratum corneum conductance may have a major role in the large increase of oxygen flux with temperature.

Future Plans—These findings open new possibilities for investigation of cutaneous blood flow and oxygen transfer in patients with peripheral vascular disease. For example, the use of local hyperbaric oxygen to treat skin ulcers might be enhanced by raising the local skin temperature and providing a high humidity during hyperbaric treatments. We will explore this idea initially as a pilot project in the coming year.

We have taken delivery of a Liebold helium mass spectrometer and have ordered the supplies and components necessary to use it for skin blood flow measurements.

Sponsoring Agencies and Organizations

American Paralysis Association

McLean, VA 22101
Richard Van Oden, President

In section **IV. Spinal Cord Injury, I. Functional Electrical Stimulation, 1. General**:
- External Control of the Neuromuscular System.

In section **IV., I. Functional Electrical Stimulation, 4. Other**:
- Spasticity Suppression with High Frequency Electrical Stimulation.

Mohamed A.M.M. Atia

Mehalla-Kubra, Egypt

In section **XV. Miscellaneous**:
- Treatment of Peripheral Arteriosclerosis with Diadynamic Current.

Chas. A. Blatchford & Sons, Ltd., Research and Development Unit

Hampshire RG 22 4LU, England
J.J. Shorter, Technical Director

In section **I. Amputations and Limb Prostheses, B. Lower Limb, 1. General**:
- ENDOLITE—The High Technology Prosthesis.

Catholic University of Louvaine, Fund for Scientific Research, Office of Science Policy

Brussels, Belgium

In section **XIII. Sensory Aids, A. Blindness and Low Vision, 2. Mobility Aids**:
- Design and Evaluation of Sensory Substitution Systems.

Commonwealth Department of Health (Australia)

New South Wales, Australia

In section **XIV. Head Trauma and Stroke**:
- Computer Program for Brain Injury Evaluation.

Department of Veterans Affairs, Central Development Unit

South Melbourne, Victoria, Australia
Marius Fahrer, M.D., F.R.A.C.S., Director

In section **I. Amputations and Limb Prostheses, A. General**:
- Flexible Sockets for Prostheses.

In section **I., C. Upper Limb, 1. General**:
- Orthoses and Prostheses for Partial Hand Amputation/Evaluation of the Hosmer Contour Terminal Device.

In section **XI. Low Back Pain**:
- Inversion Therapy for Low Back Pain in Elderly Patients.

Easter Seal Research Foundation, National Easter Seal Society

Chicago, IL 60612
Rita McGaughey, Associate Director

In section **IV. Spinal Cord Injury, E. Communication Methods and Systems for the Severely Disabled**:
- PACA — Portable Anticipatory Communication Aid.

Ethicon/Johnson & Johnson

Somerville, NJ 08876
Frank G. Fitzpatrick, President

In section **VII. Wound and Fracture Healing**, non-designated funds were provided for:
- Enhancement of Wound Healing Using Synthetic Skin, Electrical Stimulation, and Hyperbaric Oxygen Therapy.

Institute of Physical and Chemical Research, Office for Life Science Promotion

Agency of Science and Technology of the Japanese Government
Tokyo 162, Japan
Yasuhisa Sakurai, Director

In section **II. Orthotics, A. Lower Limb**:
- Development of a Powered Orthosis for Lower Limbs.

Israel Ministry of Defence, Technion-Israel Institute of Technology

Haifa, Israel

In section **I. Amputations and Limb Prostheses, B. Lower Limb, 2. Below-Knee**:
- Comprehensive Alignment Procedure of Below-Knee Artificial Leg.

In collaboration with the **Segal Foundation** and the **Technion VPR Fund/W. Levenson Fund for Biomedical Engineering Research**, section **IV. Spinal Cord Injury, I. Functional Electrical Stimulation, 3. Lower Limb Functions**:
- Biomechanical and Physiological Evaluation of Paraplegics Activated by Functional Electrical Stimulation.

Supported by the **Doron Foundation for Education and Welfare** and the **Technion VPR Fund/W. Levenson Fund for Biomedical Engineering Research**, section **III. Total Joint Replacement and Other Orthopaedic Implants, C. Knee**:
- Minimal-Gliding Knee Endoprosthesis.

Supported by the **Technion-Israel Institute of Technology**, section **I. Amputations and Limb Prostheses, C. Upper Limb, 1. General**:
- Considerations for New Design of Human Hand Prosthesis.

Langer Biomechanics, Inc.

Hines, IL 60141

In section **VI. Biomechanics, C. Human Locomotion and Gait Training**:
- Weight Distribution in the Foot Before and After Surgical and Orthotic Intervention for Hallux Rigidus.

Liberty Mutual Insurance Company, The NeuroMuscular Research Center, Boston University

Boston, MA 02215
Carlo J. De Luca, Ph.D., Director

In section **VI. Biomechanics, E. Other**:
- Control of Posture; and
- Postural Sway in Down's Syndrome.

In section **VIII. Properties of Muscles, B. Muscle Contraction**:
- The Myoelectric Signal Decomposition Technique;
- Motor Unit Firing Rates and Recruitment;
- Synchronization of Motor Unit Discharges;
- Control of Antagonist Muscles;
- Control of Synergist Muscles; and
- Motor Control in Movement Disorders (cosponsored with the **VA**).

In section **VIII., C. Muscle Fatigue**:
- Muscle Fatigue and the Myoelectric Signal (cosponsored with the **VA**).
- The Muscle Fatigue Monitor;
- Muscle Fiber Conduction Velocity;
- Effects of Surface Electrode Location on the Myoelectric Signal Parameters;
- Muscle Fatigue and Back Pain;
- Myobeeper; and
- Topical Anesthesia and Muscular Hypertonicity.

In section **XI. Low Back Pain**:
- Objective Evaluation of Muscle Fatigue in the Trunk.

Louisiana Department of Health and Human Resources

New Orleans, LA 70112
Daniel Bardsley, Assistant Secretary

In section **IV. Spinal Cord Injury, F. Environmental Control Systems for the Severely Disabled**:
- Reinforcement of Voluntary Head Control.

In section **IV., G. Wheelchairs, Including Seating and Controls**:
- Seating System for Patients with Multiple Spinal Deformities.

National Institute for Health and Medical Research, National Agency for Research Valorization

Hospital Henri Rousselle
75674 Paris CEDEX 14
France

In section **XIII. Sensory Aids, A. Blindness and Low Vision, 1. General**:
- Project Poly-Son: A Computer Sound Peripheral Device for Visually Handicapped Children and Adolescents.

National Institute of Handicapped Research, Department of Education

Washington, D.C. 20202-2305

Richard Leclair, Acting Director

In section **I. Amputations and Limb Prostheses, C. Upper Limb, 1. General**:

- Quantification of the Functional Capability of Upper Extremity Amputees;
- Feasibility for Innovation and Improvement of Body-Powered Upper Limb Prostheses; and
- Myoelectric Prosthetic System.

In section **III. Total Joint Replacement and Other Orthopaedic Implants, A. General**:

- Development of Biologic Cement for Fixation of Skeletal Implants;
- Investigation of the Bone/Bone Cement/Implant Interface Formed by Total Joint Replacement; and
- Vacuum Mixing of Acrylic Bone Cement.

In section **III., C. Knee**:

- Interaction of Total Knee Replacement Geometry with Knee Ligaments;
- Design and Evaluation of Knee Orthoses; and
- Prospective Clinical Study of the Kinematic Knee.

In section **IV. Spinal Cord Injury, A. General**:

- Treatment of Central Pain in Spinal Cord Injury: A Pilot Study;
- Retrospective Analysis of the National Spinal Cord Injury Care System Database;
- Pain Secondary to Gunshot Wound During the Initial Rehabilitation Process in Spinal Cord Injury Patients;
- P.L. 480 Paraplegia Project, Madras, India;
- Outcome Studies Pertinent to the National Model Spinal Cord Injury System;
- Longitudinal Assessment of Physical Therapy Factors in the Rehabilitation Process that Affects the Quality of Life of Persons with Spinal Cord Injury;
- Assessment, Development, and Clinical Applications of Strategies to Coordinate Services for Spinal Cord Injured Clients After Discharge;
- Documenting and Utilizing Programs Which Provide Community Adjustment and Independent Living Services for Persons with Spinal Cord Injury;
- Vocational Evaluation for Quadriplegics with a High School Education or Less;
- Development of a Reconditioning Exercise Program for Patients with Paraplegia; and
- Longitudinal Assessment of the Utilization of Upper Extremity Assistive Devices Prescribed for the Spinal Cord Injured Quadriplegic.

In section **IV. B. Medical Treatment**:

- An Ultrasonic Bladder Sensor for Persons with Incontinence;
- Natural History and Clinical Course of Urinary Tract Complications in Patients with Spinal Cord Dysfunction;
- Effectiveness of Prophylactic Anti-Microbial Therapy in Patients with Neurogenic Bladder;
- Differential Renal Function in Patients with Neurogenic Bladder;

- Determinants of Renal Function Alterations During Long-Term Follow-Up in Patients with Spinal Cord Dysfunction Using Radionuclide Procedures;
- Effect of Body Position on Total Lung Compliance in the Traumatic Quadriplegic;
- High Frequency Jet Ventilation in Patients With Spinal Cord Dysfunction: A Study of Patients with Respiratory Insufficiency Secondary to Cervical Lesions;
- Effects of Spinal Cord Injury on Drug Metabolism;
- Didronel in the Prevention of Heterotopic Ossification Following Spinal Cord Injury: Determination of an Optimal Treatment Schedule;
- Incidence and Clinical Significance of Impaired Brain Function in Spinal Cord Injury: A Continuing Preliminary Study;
- Incidence, Characteristics, and Clinical Significance of Anemia in Patients With Spinal Cord Dysfunction; and
- The Relationship of Nutritional Status and the Occurrence of Secondary Complications in Spinal Cord Injury Patients.

In section **IV., D. Independent Living for the Severely Disabled:**

- Promoting Consumer Involvement;
- Involving Disabled Consumers in Community Change;
- Training Attendant Care Management Skills;
- Encouraging Dignified Service Provision;
- Promoting Community Support for Independent Living;
- Improving Media Portrayals of Persons With Disabilities;
- Evaluating the Impact of ILCS;
- Extending Independent Living to New Populations;
- Social Support Systems for Enhancing Independent Living; and
- Program in Social and Independent Living Skills.

In section **IV., E. Communication Methods and Systems for the Severely Disabled**:

- MICRODEC II — Environmental Control Systems and Computer Access Aids; and
- An Optimal, Inexpensive Text Entry System for the Orthopedically and Neurologically Disabled.

In section **IV., G. Wheelchairs, Including Seating and Controls**:

- University of Virginia Rehabilitation Engineering Center.

In section **IV., I. Functional Electrical Stimulation, 1. General**:

- Neuroaugmentive Procedures for Modification of Abnormal Motor Control in Patients with Spinal Cord Injury.

In section **V. Functional Assessment**:

- Improved Methods of Quantification of Function/Performance;
- Development of a Computer-Automated System for Functional Assessment;
- Clinical Evaluation and Application of a Computer-Automated System for Functional Assessment (Part I and Part II);
- Measurement of Muscle Strength, Endurance, and Range of Motion;
- Quantitative Measures for Assessing Gait;
- Quantification Mobility Performance for Functional Assessment, Diagnosis, and Therapy of Neuromuscular, Skeletal, and Synovial Joint Dysfunctions; and

- Predictive Assessment in Prescription of Functional Aids for the Motor-Disabled.

In section **VI. Biomechanics, C. Human Locomotion and Gait Training**:

- A Telemetric Data Acquisition and Processing System for Biofeedback Training and as a Diagnostic Aid for Human Movement Training; and
- Evaluation of Methods to Measure Locomotion Performance and Activity.

In section **X. Arthritis**:

- Arthritis Rehabilitation Unit; and
- Impact of Arthritis Self-Care Programs for Rural Persons.

In section **XI. Low Back Pain**:

- Low Back Pain Prevention, Rehabilitation, and High Risk Inventory Development;
- Myoelectric Analysis of Human Spine Function; and
- The Vermont Rehabilitation Engineering Center for the Study of Low Back Pain.

In section **XIII. Sensory Aids, A. Blindness and Low Vision, 1. General**:

- Demonstration of a Low Vision Aid Clinic as an Employment Enhancement Technique;
- Industrial Services Program Model for Sheltered Workshops for Legally Blind Workers;
- Assessment of Current Career Development Intervention Services and the Needs of Blind and Severely Visually Impaired Individuals;
- Functional Outcome for Blind or Severely Visually Impaired Clients of State Rehabilitation Agencies;
- Illumination Level and Color Contrast Studies;
- Development of Electromechanical Vocational Assessment Technology for Finger Dexterity and Hand/Foot Coordination;
- Adaptation of the Vocational Educational Readiness Test;
- Training Opportunities Profile for Visually Impaired Persons;
- Pre-Vocational Work Ability and Success-Acquisition Training of Deaf-Blind and Other Multiply Visually Disabled Individuals;
- Assessment of Eye-Hand Coordination and Manual Dexterity Under Different Illumination Levels and Contrast Conditions;
- Selected Career Development Factors and Outcome of Vocational Rehabilitation Services Provided Middle-Aged and Older Blind Persons; and
- Sensory Aid Technology: A Career Development Intervention Strategy for Blind and Severely Visually Impaired Persons.

In section **XIII., A. Blindness and Low Vision, 2. Mobility Aids**:

- Expansion of a Computerized Information System for Use in the Study of Low Vision Mobility;
- Illumination and Mobility;
- The Spatial Orientation of Low Vision Persons;
- The Mobility of Persons with Low Vision;
- The Effects of Low Vision Aids and Training Materials on Mobility Performance and Stress;
- Evaluation of Travel Skills of Visually Impaired Veterans; and

- The Evaluation of Low Vision Aids and Prediction of Visual Performance Through Low Vision Aids.

In collaboration with the **Smith-Kettlewell Institute of Visual Sciences**, NIHR conducted the following research on blindness and low vision.

In section **XIII. Sensory Aids, A. Blindness and Low Vision, 1. General**:

- Microprocessor-Based Job Instrumentation;
- Auditory Breakout Box;
- Blind Technicians Training Program;
- Telephone Assembly Technician;
- Evaluation of Computer Hardware and Software for Visually Impaired Persons;
- Commercialization of Earlier Products;
- Pediatric Program;
- Geriatric Research;
- Aids for the Deaf-Blind;
- Oculo-Encephalographic Communication System;
- New Volatile Braille Display;
- New Ways to Access Microprocessor- and Computer-Based Aids;
- Microprocessor- and Computer-Based Aids;
- Form Board; and
- Portable Electronic Braille Note-Taker.

In section **XIV. Head Trauma and Stroke**:

- Patterns of Recovery in Traumatic Brain Injury and Stroke Patients in Two Different Service Systems;
- Spasticity Treatment and Motor Control: A Comprehensive Re-Examination;
- Retraining Proprioception Using Artificial Joint Angle Feedback and Stimulus Fading;
- Motor Copy Procedures in Improving Function of the Upper Extremities of Stroke and Traumatic Head Injury Patients;
- Forced Use in Improving Function of Upper Extremities in Traumatic Head Injured and Stroke Patients;
- Rehabilitation of Cognitive Deficits with Interactive Computer Assistance;
- The Relationship between Cognitive Status, Objective Language Skills, and Functional Language During Recovery from Severe Head Injury;
- Social Skills Training as a Facilitator of Adjustment to Traumatic Head Injury;
- Increased Self-Control in Closed Head Injury Patterns in Multiple Environments with Family Intervention;
- Nutritional Assessment of Closed Head Injury Patients (on Hold); and
- Family Factors and Work Adjustments of Handicapped Mexican American Disabled.

In section **XV. Miscellaneous**:

- Development of a Life Satisfaction Scale Applicable for People with Severe Disabilities;
- Minimizing Occupational Barriers for Physically Handicapped Farmers and Agricultural Workers;

- Extending the Management Control Project: Assessing Impact, Outcome, and Client Satisfaction;
- How the Congenitally/Physically Deformed Learn to be Independent;
- Job Club;
- Stimulation of Industry and Evaluation of Technology; and
- Predictive Criteria in Rehabilitation of ESRD Patients.

National Institutes of Health

Bethesda, MD 20892

James Wyngaarden, M.D., Director

In section **II., Orthotics, B. Upper Limb**:

- Retrodisplacement and Spondylolisthesis — Brace Treatment.

In section **III., Total Joint Replacement and Other Orthopaedic Implants, A. General**:

- Diagnosis of Loose or Damaged Total Joint Replacement (Human);
- Mechanisms of Orthopedic Implant Loosening (Rats);
- Ultrasonic Study of the Cement-Cancellous Bone Interface (Cattle, Human).

In section **III., B. Hip**:

- Load Transfer of Non-Fixed, Close-Fit Femoral Stems (Sheep).

In section **IV., Spinal Cord Injury, B. Medical Treatment**:

- Control of Respiratory Skeletal and Smooth Muscle;
- Reconstruction of One Level Cervical Spinal Instability (Dog);
- Spinal Cord Injury Model;
- Standardized Reproducible Spinal Cord Injury Model (Mammals);
- Radiography and Radioisotopic Angiography of Spinal Cord;
- Spinal Somesthetic Pathways (Human, Monkeys);
- National Acute Spinal Cord Injury Study (Human);
- Clinical Research Center for Acute Spinal Cord Injuries;
- A Center for Acute Spinal Cord Injury;
- Spinal Cord Injury Research Center;
- Program of Research in Spinal Cord Injury; and
- Fundamental Studies in Spinal Cord Injury.

In section **IV., C. Spinal Cord Regeneration**:

- Functional Spinal Cord Regeneration (Cats);
- Recovery and Regeneration After Spinal Neuron Injury;
- Muscle Reinnervation and Neurotrophic Influence (Anurans, Rodents).

In section **IV., E. Communication Methods and Systems for the Severely Disabled**, the **National Institute of Neurological and Communicative Disorders and Stroke** (**NINCDS**) of NIH and the **Public Health Service of the U.S. Department of Health and Human Services** cosponsored the following:

- Computer-Aided Motor Assessment and Rate Prediction for Prescription of Communication Devices; and
- A Needs-Features Spreadsheet for Communication Device Prescription.

With **Massachusetts Institute of Technology** and **Tufts University, NINCDS** cosponsored:

- Computer-Aided Assessment for Communication Rate Prediction.

In section **IV., I. Functional Electrical Stimulation, 2. Lower Limb Applications**:
- Implantable Systems for Stimulation of Skeletal Muscle (Guinea Pigs, Dogs);
- Myoelectric Controller for Orthotic/Prosthetic Systems (Cats).

In section **IV., I. Functional Electrical Stimulation, 4. Other**:
- Electrical Stimulation in Treatment of Scoliosis (Human, Cats, Sheep).

In section **VI., Biomechanics, A. Joint Studies, 1. General**:
- Control of Metrical and Timing Precision in Human Movement.

In section **VI., A. Joint Studies, 2. Lower Limb**:
- Clinical Biomechanics of the Knee-Rotatory Laxities;
- Biomechanics of Anterior Cruciate Repairs (Human);
- Biomechanics of Anterior Cruciate Ligament Reconstruction (Dogs);
- Ligamentous Knee Stability-Combined Clinical Loadings (Human); and
- Biomechanics of Hip and Knee (Human).

In section **VI., A. Joint Studies, 3. Upper Limb**:
- Static Force and Stability Analysis of Human Elbow;
- Biomechanical Study of the Radial Ulnar Carpal Joint (Human);
- Mechanics of Control of Movement of Human Elbow Joint;
- Functional Forces in Normal and Abnormal Fingers (Human); and
- Influence of Wrist Pathomechanics on Hand Function (Human).

In section **VI. Biomechanics, B. Spine**:
- Clinical Biomechanics of the Cervical Spine (Human);
- Three-Dimensional Kinematics of the Lumbar Spine (Human);
- Biomechanical Studies of Idiopathic Scoliosis (Human);
- Structural and Mechanical Properties of Spine (Human);
- Characterization of Morphologic Changes in Scoliosis;
- The Traumatology of the Head and Spine (Monkey, Human); and
- Mechanism of Cervical Spine Injuries.

In section **VI., C. Human Locomotion and Gait Training**:
- Quantitative Gait Analysis (Human).

In section **VI., E. Other**:
- Human Response and Lower Extremity Injury;
- Control of Metrical and Timing Precision in Human Movement;
- Biomechanics of Human Skin; and
- Stress Analysis of Internal Fracture Fixation of Long Bones.

In section **VII. Wound and Fracture Healing**:
- Studies on Factors Affecting Orthopaedic Infections (Human, Hamsters);
- Electrical Stimulation of Mandibular Fractures (Rabbits);
- Acceleration of Fracture Healing Electrical Fields (Rabbits, Rats).

In section **VIII. Properties of Muscles, A. General**:
- Quantification of Dynamic Muscle Strength (Human);
- Muscle Structure and the Contractile Mechanism (Rabbits, Protozoa);
- Alterations in Skeletal Muscle with Use and Disuse (Rats);
- Elasticity, Force, and Fiber Length Changes in Aging Muscle (Rats).

In section **IX. Ligaments and Tendons**:
- Anterior Cruciate Ligament Healing (Dogs, Rabbits);
- Exercise Effects on Tendon Repair (Rabbits, Chickens); and

• Affects of Immobilization and Motion in the Injured Tendon (Chicken).

In section **X. Arthritis**:

• Investigations of Osteoarthritis and Bone Loss;
• Illness Cognition and Coping in the Elderly (Human);
• Multipurpose Arthritis Center, Northwestern University;
• Robert B. Brigham Multipurpose Arthritis Center;
• UCSF Multipurpose Arthritis Center;
• Multipurpose Arthritis Center, University of Missouri;
• Multipurpose Arthritis Center, Downstate Medical Center;
• Multipurpose Arthritis Center, University of Connecticut Health Center;
• Multipurpose Arthritis Center, University of Alabama at Birmingham;
• Multipurpose Arthritis Center, Boston University;
• Multipurpose Arthritis Center, Indiana-Purdue Universities;
• University of Michigan Multipurpose Arthritis Center;
• Northeast Ohio Arthritis Center Support; and
• A National Arthritis Data Source (ARAMIS).

In section **XIII., Sensory Aids, A. Blindness and Low Vision, 1. General**:

• Princeton Cutaneous Research Project.

The **National Institute of Neurological and Communicative Disorders and Stroke (NINCDS)** of NIH conducted the following research.

In section **XIII., Sensory Aids, B. Deafness and Hearing Impairment**:

• Phoneme Confusions Associated with Room Reverberation, Age, and Hearing Loss;
• Matching Speech to Residual Auditory Function (Human);
• Communicative Disorders Clinical Research Center;
• Effects of Aging Upon Communication;
• Auditory Communication and Its Disorders;
• Clinical Research Center for Communication Disorders;
• High-Frequency Acoustics in the External Human Ear;
• Rehabilitation Strategies for the Hearing Impaired Person;
• Multimicrophone Monaural Aids for the Hearing Impaired Person;
• Hearing Aids and Rehabilitation for Hearing Loss;
• Hearing Aid Characteristic Selection;
• Suprathreshold Auditory Behavior;
• Development of a Cochlear Prosthesis; and
• Auditory Communication and Its Disorders.

In section **XIII., C. Speech Impairment**:

• Development of a Procedure to Guide Prescription of Devices for Severely Speech-Impaired Clients (in collaboration with New England Medical Center Hospitals and Massachusetts Institute of Technology).

In section **XIV. Head Trauma and Stroke**:

• Studies of Spasticity in Brain-Injured Patients;
• Spasticity — Mechanisms and Quantification (Human);
• Establishment of a Central Nervous System Trauma Center (U. of CA);
• Establishment of a Central Nervous System Trauma Center (Yeshiva U.); and
• Establishment of a Central Nervous System Trauma Center (U. of TX).

In section **XV. Miscellaneous**:

• Laryngeal Function in Normal and Abnormal Speech (Human).

In collaboration with the **Ben Franklin Partnership Program of the Commonwealth of Pennsylvania**, the **National Heart, Lung, and Blood Institute** of NIH conducted the following research:

- Gas Flux Human Skin: Effect of Temperature, Stripping, and Inspired Tension.

National Rehabilitation Center for the Disabled

Namiki, Tokorozawa, Saitama, Japan

In section **VI. Biomechanics, C. Human Locomotion and Gait Training**:

- Biomechanical Study of Standing and Walking Using Force Plate.

National Science Foundation, Bioengineering and Research for the Handicapped Program

Washington, D.C. 20550
William Freedman, Director

In section **I. Amputations and Limb Prostheses, B. Lower Limb, 3. Above-Knee**:

- Microcomputer-Controlled Individualized, Multimode Prostheses for Lower Extremity Amputees.

In section **III. Total Joint Replacement and Other Orthopaedic Implants, A. General**:

- Intermolecular Bonding and Microphase Separation in Polyurethane Block Polymers.

The Frances and Augustus Newman Foundation and Head Injury Recovery Trust

Bristol, BS16 1QT, England

In section **XIV. Head Trauma and Stroke**:

- A Program for the Cognitive Rehabilitation of the Head Injured.

Northern Ireland Prosthetics, Orthotics, and Aids Service

Rehabilitation Engineering Centre
Musgrave Park Hospital
Belfast, Ireland

In section **III. Total Joint Replacement and Other Orthopaedic Implants, A. General**:

- Examination of Implants by Photoelastic Techniques.

In section **XII. Muscular Dystrophy**:

- An Arm-Lifting Device.

In section **VI. Biomechanics, C. Human Locomotion and Gait Training**:

- A Low-Cost Gait Recording System.

Osaka Rosai Hospital, Department of Rehabilitation

Osaka, 591, Japan

In section **I. Amputations and Limb Prostheses, B. Lower Limb, 3. Above-Knee**:

- Biomechanical Evaluation of ISNY Flexible Socket;
- Sensory Feedback System for Above-Knee Prosthesis; and
- Evaluation of Load-Actuated-Brake Knee for Above-Knee Prosthesis.

In section **IV. Spinal Cord Injury, I. Functional Electrical Stimulation, 1. General**:
- Functional Neuromuscular Stimulation for Quadriplegic Patients.

In section **VIII. Properties of Muscles, A. General**:
- Evaluation of Spasticity.

Ossur h.f., Prosthetics/Orthotics

125 Reykjavik, Iceland
Ossur Kristinsson, C.P.O.

In section **I. Amputations and Limb Prostheses, B. Lower Limb, 1. General**:
- The ICEROSS System; and
- The ICEPOSS System.

Paralyzed Veterans of America, Spinal Cord Research Foundation

Washington, D.C. 20006
Lynn Phillips, Director

In section **IV. Spinal Cord Injury, A. General**:
- Aging and Spinal Cord Injury: Research Needs Study;
- Diagnosis and Treatment Compatible Spinal Cord Injury Patient Stabilization and Transport Devices;
- Economic Consequences of Severe Disability; and
- Acute Spinal Injury Patient Transportation and Support Devices.

In section **IV., B. Medical Treatment**:
- A Practical Method of Relaxing the Neck of the Bladder and the External Sphincter of the Urethra Which Permits Voiding in Paraplegic Cats;
- Bronchial Mucus Secretion in Acute Quadriplegia: A Qualitative Study;
- Pharmacokinetics of Drugs in Spinal Cord Injured Persons;
- Actions and Metabolism of TRH in the Spinal Cord;
- Factors Affecting Sodium and Water Homeostasis in Spinal Cord Injury;
- A Laboratory Test to Predict and Monitor Bone and Skin Related Complications in Spinal Cord Injured Patients;
- Evaluation and Rehabilitation of Reproductive Function in Paraplegia;
- Role of Antidiuretic Hormone in Cardiovascular Responses to Postural Change in Quadriplegic Subjects;
- Prediction of Spared Motor Pathways and Recovery from Injury Using the Motor Evoked Potential in a Spinal Cord Impact Model;
- Diglycerides and Phosphatidic Acid in Peripheral Nerve and Spinal Cord During Wallerian Degeneration; and
- Spinal Cord Explants Cultured on Carbon Filaments and Stimulated with Direct Current.

Also in this section and cosponsored by PVA's **Technical and Research Foundation** and **NIHR**:
- Collagen Dysfunction in Quadriplegia.

In section **IV., C. Spinal Cord Regeneration**:
- Trophic Interactions Between Nerve Terminals and Their Target Tissues;
- Studies of CNS Regeneration: Changes in the Astrocyte Cell Surface Membrane Following CNS Injuries and During Development;
- Axon Regeneration in the Mammalian Spinal Cord in Response to Surgical

Denervation and Nerve Growth Factor;
- Axonal Regeneration in the Adult Spinal Cord;
- Protein Transport in Injured CNS Axons; and
- Central Nervous System Regeneration in Nerve Grafts.

In section **IV., F. Environmental Control Systems for the Severely Disabled**, cosponsored with the **VA Rehabilitation Research and Development Service**:
- Ultra Sonic Head Control Interface (UHCI).

In section **IV., G. Wheelchairs, Including Seating and Controls**:
- Mapping the Buttock-Cushion Interface with Ultrasound: Significance in Seating for Pressure Sore Prevention.

In section **IV., H. Personal Licensed Vehicles**:
- Adaptive Systems for Disabled Ultralight Pilots.

In section **IV., I. Functional Electrical Stimulation, 1. General**:
- Neurophysiological Assessment of Changes Induced by Neuromuscular Electrical Stimulation in Stabilized SCI Patients; and
- Influence of Continuous Electrical Stimulation on the Spinal Cord Motor Neurons.

In section **IV., I. Functional Electrical Stimulation, 4. Other**:
- Predictive Factors for Restrengthening Paralyzed Muscle by Electrical Stimulation.

In section **XV. Miscellaneous**:
- Serum Antimyelin Activity in Chronic Relapsing Experimental Allergic Encephalomyelitis.

Regency Park Centre for Young Disabled

Kilkenny, S.A., 5009, Australia

In section **IV. Spinal Cord Injury, D. Independent Living for the Severely Disabled**:
- Technology to Enhance Independence of Physically Disabled School Children.

In section **IV., E. Communication Methods and Systems for the Severely Disabled**:
- Voice Control for Disabled Children.

In section **IV., G. Wheelchairs, Including Seating and Controls**:
- Wheelchair Seating Effectiveness and Wheelchair Performance.

In section **IV., I. Functional Electrical Stimulation, 1. General**:
- Functional Electrical Stimulation.

In section **XII. Muscular Dystrophy**:
- A Study of the Mechanism of Spinal Collapse in Duchenne Muscular Dystrophy.

With funding through the **Department of Transport, Government of South Australia**, in section **IV. Spinal Cord Injury, G. Wheelchairs, Including Seating and Controls**:
- Developing Safety Standards for Wheelchair Occupants in Vehicles.

With funding through **Channel 10 Children's Medical Research Foundation of South Australia, Inc.**, in section **V. Functional Assessment**:
- Skill Evaluator and Trainer.

Research Centre for the Education of the Visually Handicapped, University of Birmingham

Birmingham, England
M.J. Tobin, Director

In section **XIII. Sensory Aids, A. Blindness and Low Vision, 1. General**:
- Implementing Micro-Technology and Computer-Assisted Learning;
- Assessing the Manual Dexterity of the Blind; and
- Blind in Birmingham — A Pilot Survey of Knowledge of Available Services.

In section **XIII., A. Blindness and Low Vision, 2. Mobility Aids**:
- A "Moon" Writer.

Royal Institute of Technology, Department of Speech Communication and Music Acoustics

Stockholm S-100 44, Sweden

In section **XIII., A. Blindness and Low Vision, 2. Mobility Aids**:
- Speech Transmission Laboratory Quarterly Progress and Status Report.

In section **XIII., C. Speech Impairment**:
- Technical Aids for the Speech-Impaired Person; and
- Lexical Prediction for a Text-to-Speech System.

Royal National Institute for the Blind

London WIN 6AA, England

In section **XIII. Sensory Aids, A. Blindness and Low Vision, 1. General**:
- Survey of Local Authority Social Rehabilitation Services for Visually Handicapped Adults.

Scientific and Research Trust of the Central Remedial Clinic

Dublin 3, Ireland

In section **IV. Spinal Cord Injury, F. Environmental Control Systems for the Severely Disabled**:
- The Development of Environmental Control Systems for the Severely Physically Disabled.

In section **VI. Biomechanics, C. Human Locomotion and Gait Training**:
- Assessment of the Effectiveness of Gait in Cerebral Palsy Children.

In section **XII. Muscular Dystrophy**:
- Emotional Disorder Associated with Duchenne Muscular Dystrophy.

Scottish Home and Health Department

Dundee DD5 1AG, Scotland

In section **I. Amputations and Limb Prostheses, A. General**:
- A Bibliographic Database and Information Retrieval System to Prosthetics and Orthotics.

In section **I., B. Lower Limb**:
- The Development of a Computer-Aided Measurement System for Prosthetic Applications.

In section **IV. Spinal Cord Injury, G. Wheelchairs, Including Seating and Controls**:

- Pressure Sores, Blood Rheology, and the Mechanical Properties of Soft Connective Tissues.

Sinclair Research Ltd.

Cambridge, England

This project took place at research centers in Konstancin and Warszawa, Poland. In section **II. Orthotics, A. Lower Limb**:

- The LETOR System for Lower Limb Support and Locomotion Assessment.

Spinal Injuries Research Fund of the Spinal Research Foundation

Government Insurance Office
St. Leonards 2065, N.S.W., Australia

J.D. Yeo, Director

In section **IV. Spinal Cord Injury, A. General**:

- Spinal Cord Studies.

Smith-Kettlewell Institute of Visual Sciences, Medical Research Institute

San Francisco, CA 94115
Arthur Jampolsky, M.D., Director

In collaboration with the **National Institute of Handicapped Research**, projects sponsored are listed on page 369.

United Cerebral Palsy of New Orleans

New Orleans, LA 70123
Dominic MacCormack, Director

In section **I. Amputations and Limb Prostheses, C. Upper Limb, 1. General**:

- Multifunctional, Compliance Hand Prostheses — The LSU Spider Hand.

In section **II. Orthotics, A. Lower Limb**:

- Electromechanical Walking System for Paraplegics;
- A Viscoelastic Knee Brace for Anterior Cruciate Ligament Deficient Knee; and
- Analysis and Design of Optimal Halo Systems.

Sponsored by the **Louisiana Center for Cerebral Palsy**, in section **IV. Spinal Cord Injury, I. Functional Electrical Stimulation, 3. Lower Limb Applications**:

- Electrical Stimulation in Cerebral Palsy Hypotonia.

U.S. Social Security Administration

Baltimore, MD 21235
Martha McSteen, Commissioner

In section **XV. Miscellaneous**:
- Rehabilitation International Study on Social Security Benefits for Disabled Persons.

University of Strathclyde, Bioengineering Unit, Wolfson Centre

Glasgow G3 ONW, Scotland
J.P. Paul, Head of Department

In section **I. Amputations and Limb Prostheses, B. Lower Limb, 1. General**:
- Biomechanical Evaluation of Prosthetic Feet;
- Prosthetic Loading Data for the Development of Standards for Lower Limb Prostheses; and
- Study of Alignment in Lower Limb Prostheses.

In section **I., B. Lower Limb, 3. Above-Knee**:
- Survey of Prosthetic Knee Joint Design Criteria.

In section **II. Orthotics**:
- Load Analysis of Knee-Ankle-Foot Orthoses.

In section **IV. Spinal Cord Injury, I. Functional Electrical Stimulation, 3. Lower Limb Applications**:
- Restoration of Locomotion in SCI Patients Using FES.

With funding through the **Scottish Home and Health Department**, in section **IV., G. Wheelchairs, Including Seating and Controls**:
- Pressure Sores, Blood Rheology, and the Mechanical Properties of Soft Connective Tissues.

With funding through the **Multiple Sclerosis Society of the United Kingdom**, in section **VIII. Properties of Muscles, A. General**:
- Measurement and Reduction of Spasticity.

Veterans Administration

Washington, D.C. 20420

In section **IV. Spinal Cord Injury, G. Wheelchairs, Including Seating and Controls**:
- Wheelchair Usage Monitors.

Veterans Administration, Department of Medicine and Surgery, Rehabilitation Research and Development Service

Washington, D.C. 20420
Margaret J. Giannini, Director

Audiology Research Program
Dorn Veterans Hospital
Columbia, SC 29201

In section **XIII. Sensory Aids, B. Deafness and Hearing Impairment:**
- Implementation of Digital Measurement of Aural Acoustic Immittance.

Albert Einstein College of Medicine
Bronx, NY 10461

In section **IV. Spinal Cord Injury: F. Environmental Control Systems for the Severely Disabled**:
- Training Capuchin Monkeys to Serve as Aides for High Level Quadriplegics.

Georgia Institute of Technology
Atlanta, GA 30322

In section **XIII. Sensory Aids, A. Blindness and Low Vision, 1. General**:
- The Use of the Electroretinalgram to Predict Retinal Cell Activity.

Department of Orthopaedic Surgery
Johns Hopkins University School of Medicine
Baltimore, MD 21205

In section **IV. Spinal Cord Injury, F. Environmental Control Systems for the Severely Disabled**:
- Wheelchair Control and Robot Arm/Work Table System for High Spinal Cord Injured Persons.

New York University Medical Center
New York, NY 10016

In section **I. Amputations and Limb Prostheses, B. Lower Limb, 2. Below-Knee**:
- Development of the ISNY Flexible Socket System for Below-Knee Amputees.

In section **I., B. Lower Limb, 3. Above-Knee**:
- Geriatric Prosthetics: Design and Development of an Improved Above-Knee Socket.

In section **IV. Spinal Cord Injury, I. Functional Electrical Stimulation, 1. General**:
- EMG as Force-Feedback in Closed-Loop Functional Electrical Stimulation.

Prosthetics Research Laboratory
Northwestern University
Chicago, IL 60611

In section **I. Amputations and Limb Prostheses, B. Lower Limb, 1. General**:
- Computer-Aided Alignment of Lower Limb Prosthesis and "Expert" Systems.

In section **I., B. Lower Limb, 2. Below Knee**:
- Computer-Aided Analysis of Below-Knee Socket Pressure.

In section **I., B. Lower Limb, 3. Above-Knee**:
- Design of Prehension Systems for Upper Limb Amputees; and
- Position-Servo Control of Upper Limb Powered Prostheses.

In section **I., C. Upper Limb, 2. Below-Elbow**:
- Below-Elbow Prosthetic System.

University of Arkansas
Fayetteville, AR 72701

In section **XIII. Sensory Aids, C. Speech Impairment**:
- Tongue-Initiated Speech Prosthesis for the Laryngectormy.

Speech and Hearing Center
Department of Speech Communication
University of Texas
Austin, TX 78712

In section **XIII. Sensory Aids, B. Deafness and Hearing Impairment**:
- Development of Materials for Computer-Assisted Instruction in Lipreading.

University of Utah School of Medicine
Salt Lake City, UT 84132

In section **VI. Biomechanics, A. Joint Studies, 2. Lower Limb**:
- Biomechanical Comparison of Total Elbow Replacement Prostheses; and
- Mechanical Function of the Repaired Meniscus.

University of Virginia
Department of Orthopaedics and Rehabilitation
Charlottesville, VA 22908

In section **I. Amputations and Limb Prostheses, B. Lower Limb, 1. General:**
- Development of Improved Sockets for Lower Limb Amputees.

University of Washington
Seattle, WA 98195

In section **I. Amputations and Limb Prostheses, A. General:**
- Morphological and Clinical Studies of Microwounds in Ischemic Human Tissue.

In section **VII. Wound and Fracture Healing**:
- Altered Collagen and Wound Metabolism in Non-Healing Diabetic Ulcers; and
- Morphological and Clinical Studies of Microwounds in Ischemic Human Tissue.

VA Medical Center
Birmingham, AL 35233

In section **XIII. Sensory Aids, C. Speech Impairment:**
- Efficacy of Remote Delivery of Aphasia Treatment by Tel-Communicology.

VA Medical Center
Tucson, AZ 85723

In section **I. Amputations and Limb Prostheses, A. General**:
- Comprehensive Management of Upper and Lower Extremity Amputation.

In section **IV. Spinal Cord Injury, B. Medical Treatment**:
- Residual Bladder Volume Determination for Spinal Cord Injury Patients.

VA Medical Center
La Jolla, CA 92103

In section **III. Total Joint Replacement and Other Orthopaedic Implants, A. General**:
- Implant Fixation by Post-Insertion Pressurization of Polymethylmethacrylate.

VA Medical Center
Loma Linda, CA 92357

In section **I. Amputations and Limb Prostheses, B. Lower Limb, 2. Below-Knee**:
- Optimum Prosthetic Foot Characteristics for Dysvascular Below-Knee Amputees.

In section **IV. Spinal Cord Injury, I. Functional Electrical Stimulation, 3. Lower Limb Applications**:
- Weight Transfer Training Using Biofeedback and Electrical Stimulation in Strokes and Incomplete Spinal Cord Transections.

VA Medical Center
Long Beach, CA 90822

In section **XIII. Sensory Aids, C. Speech Impairment**:
- Effects of Real-Time Biofeedback on Dysarthric Speech.

In section **XV. Miscellaneous**:
- Nerve Conduction Velocity Study of the Palmar Cutaneous Branch of the Median Nerve; and
- Serial Short Segment Stimulations (Inching) of Ulnar Nerve at the Elbow in Normal Subjects and in Neuropathy.

VA Medical Center
Los Angeles, CA 90073

In section **III. Total Joint Replacement and Other Orthopaedic Implants, B. Hip**:
- Total Hip Biotelemetry.

VA Medical Center
Palo Alto, CA 94304

In section **III. Total Joint Replacement and Other Orthopaedic Implants, B. Hip**:
- Design Stress Analysis of Porous Ingrowth Hip Replacement.

In section **III., C. Knee**:
- Design Concepts for Porous Ingrowth, Prosthetic, Tibial Component.

In section **IV. Spinal Cord Injury, B. Medical Treatment**:
- Evaluation and Rehabilitation of Reproductive Function in Paraplegia.

In section **IV., F. Environmental Control Systems for the Severely Disabled**:
- Long-Term Health Care Applications for Robotic Technology;
- Interactive Evaluation of Artificial Vision with Robotic Aids for Individuals with Disabilities;
- Training Methodology and Results for a Voice-Controlled Robotic Aid;
- A Formulation of the Interactive Evaluation Model;
- Factors in the Design and Development of an Interactive Human-Robot Workstation; and
- Ultrasonic Head Control Interface (UHCI).

In section **IV., G. Wheelchairs, Including Seating and Controls**:
- The Sunburst Tandem;
- Optimal Biomechanical Design Development of Arm-Powered Mobility Vehicles;
- Skin Blood Flow Under External Loading; and
- Seating Systems for Body Support and Prevention of Tissue Trauma.

In section **IV., I. Functional Electrical Stimulation, 3. Lower Limb Applications**:
- Computer Models for Designing FES Systems for Paraplegic Standing and Walking.

In section **VI. Biomechanics, B. Spine**:
- Mechanical Analysis of Cervical Spine Stabilization Techniques.

In section **VIII. Properties of Muscle, A. General**:
- Automatic Decomposition of the Clinical Electromyogram; and
- A Smart Trigger for Real-Time Neuroelectric Spike Classification.

In section **XIII. Sensory Aids, A. Blindness and Low Vision, 2. Mobility Aids**:
- Development of a Graphic Braille Display; and
- Development of a Solid-State Reading Aid for the Visually Impaired Person.

In section **XIII., C. Speech Impairment**:
- Computer-Aided Visual Communication for Severely Impaired Aphasic Persons.

In section **XV. Miscellaneous**:
- A Life-Span Approach to Product Design and Development for the Aging Population;
- Toward Better Methods of Nerve Repair and Evaluation; and
- Rehabilitation Electronic Access Project.

VA Medical Center
San Diego, CA 92161

In section **I. Amputations and Limb Prostheses, B. Lower Limb, 1. General**:
- The Effect of Gait Using Various Ankle-Foot Devices.

In section **I., B. Lower Limb, 2. Below-Knee**:
- Volume Changes Occurring in Postoperative Below-Knee Stumps; and
- Analysis of Below-Knee Suspension Systems: Effect on Gait.

In section **II. Orthotics, A. Lower Limb**:
- Foot and Shoe Interface Study.

In section **IV. Spinal Cord Injury, I. Functional Electrical Stimulation, 4. Other**:
- Skeletal Muscle Adaptation to Electrical Stimulation: Rehabilitation of Fast and Slow Skeletal Muscle; and
- Skeletal Muscle Adaptation to Electrical Stimulation: Specific Tension of Isolated Fast and Slow Muscle Fibers.

In section **IX. Ligaments and Tendons**:
- Structural and Functional Properties of Normal and Repaired Ligaments; and
- Evaluation of Tubular Internal Fixation Plate for Fracture Management.

VA Medical Center
San Francisco, CA 94121

In section **I. Amputations and Limb Prostheses, B. Lower Limb, 1. General**:
- MACH Foot Study Development; and
- SACH Foot Study.

In section **I., B. Lower Limb, 2. Below-Knee**:
- Lightweight Three Component Below-Knee Prosthesis.

In section **II. Orthotics, A. Lower Limb**:
- San Francisco Molded Shoe.

In section **III. Total Joint Replacement and Other Orthopaedic Implants, B. Hip**:
- The Efficacy of Radiolucent Low Modulus Total Hip Surface Replacement.

In section **XV. Miscellaneous**:
- Aesthesiometry in Screening and Prevention of Neurotrophic Ulcerations; and
- Thermographic/Spectroscopic Comparison of Soaks, Exercise, and Trental on Diabetic Feet.

VA Medical Center
Sepulveda, CA 91343

In section **IV. Spinal Cord Injury, G. Wheelchairs, Including Seating Systems and Controls**:
- Evaluation of Powered Wheelchairs and Their Steering Systems.

In section **XI. Low Back Pain**:
- Biobehavioral Studies of Chronic Low Back Pain.

VA Medical Center
West Haven, CT 06516

In section **XIII. Sensory Aids, B. Deafness and Hearing Impairment**:
- Clinical Trial with the Cochlear Implant Prosthesis.

VA Medical Center
Gainesville, FL 32602

In section **III. Total Joint Replacement and Other Orthopaedic Implants, B. Hip**:
- Quantitative Analysis of the Effect of Total Hip Arthroplasty on Stress and Strain in the Human Pelvis.

In section **XV. Miscellaneous**:
- Computerized Treatment of Acquired Reading Disorders.

VA Medical Center
Miami, FL 33125

In section **IV. Spinal Cord Injury, A. General**:
- The Use of EMG Biofeedback and Functional Electrical Stimulation in Spinal Cord Injury.

VA Medical Center
Atlanta, GA 30033

In section **IV. Spinal Cord Injury, G. Wheelchairs, Including Seating and Controls**:
- Alternate Transit Vehicle for the Physically Disabled Person;
- Development of a Linear Synchronous Motor for Wheelchair Use; and
- Manual Wheelchair with Anti-Rollback Wheel.

In section **IV., H. Personal Licensed Vehicles**:
- A Driving Simulator for the Physically Disabled Person

In section **XIII. Sensory Aids, A. Blindness and Low Vision, 1. General**:
- Musical Language and Large-Print Considerations in Human-Factors Engineering.

In section **XIII., A. Blindness and Low Vision, 2. Mobility Aids**:
- The VA Guide Dog Harness;
- SONA/SONA-ECS; and
- A Large-Print Word Processor for the Visually Impaired Person.

In section **XIII, C. Speech Impairment**:
- The Comprehensive Communication System for Speech Impaired Persons.

VA Medical Center
Augusta, GA 30910

In section **I. Amputations and Limb Prostheses, A. General**:
- Determination of Causes of Phantom Limb Pain.

In section **IV. Spinal Cord Injury, A. General**:
- Phantom Sensations Experienced by Complete Spinal Cord Injured Veterans.

In section **XIII. Sensory Aids, B. Deafness and Hearing Impairment**:
- Studies in Acoustic Feedback in Hearing Aids; and
- Variables Affecting Hearing Aid Performance.

VA Medical Center
Decatur, GA 30033

In section **IV. Spinal Cord Injury, F. Environmental Control Systems for the Severely Disabled**:
- Design of Bathrooms, Bathing Fixtures and Controls for Disabled and Elderly Persons.

In section **VI. Biomechanics, A. Joint Studies, 1. General**:
- Vibration Studies of Bones and Joints.

In section **VII. Wound and Fracture Healing:**:
- Electrical Stimulation for Augmentation of Wound Healing; and
- Electrical Stimulation of Osteogenesis Using Selected Techniques.

In section **XIII. Sensory Aids, A. Blindness and Low Vision, 1. General**:
- Rabbit EERG Response to White-Noise-Modulated Stimuli.

In section **XV. Miscellaneous**:
- Memory Remediation in Older Adults: A Computerized Interactive System.

VA Medical Center
Honolulu, HI 96850

In section **XIV. Head Trauma and Stroke**:
- Computer-Assisted Neuropsychological Assessment.

In section **XV. Miscellaneous**:
- Epidemiological Index of Disabled Pacific Basin Veterans.

VA Medical Center
Hines, IL 60141

In section **IV. Spinal Cord Injury, B. Medical Treatment**:
- Neural Mechanisms Underlying Bladder Dysfunction After Spinal Trauma.

In section **IV., F. Environmental Control Systems for the Severely Disabled**:
- Voice-Operated Appliance Control.

In section **IV., G. Wheelchairs, Including Seating and Controls**:
- Maintenance Free Battery;
- New Designs for Personal Lifts; and
- A Heelstrap Retractor and a Shock Absorbing Seat Suspension System for Wheelchairs.

In section **IV., I. Functional Electrical Stimulation, 4. Other**:
- Electrical Stimulation of Paralyzed Muscle After Spinal Injury.

In section **VI. Biomechanics, B. Spine**:
- Mathematical Modeling of the Human Spine: Implications to the Orthotic Management of Spinal Deformities; and
- Effects of Low Back Pain Treatment Modalities on Lumbar Facet Loading.

In section **IX. Ligaments and Tendons**:
- The L.T.W. Connective Tendon/Ligament Device.

In section **XIII. Sensory Aids, A. Blindness and Low Vision, 1. General**:
- Predicting the Visual Abilities of Partially Sighted Persons; and
- The Effectiveness of a Blind Rehabilitation Program.

In section **XIII., A. Blindness and Low Vision, 2. Mobility Aids**:
- Measuring the Mobility of Blind Travelers;
- The Effects of Preview Distance on Blind Mobility;
- Reading Aids for Blind Readers; and
- "Magic Wand," The Braille Teacher.

In section **XIII., C. Speech Impairment**:
- Portable Communication Aid with Synthetic Speech.

VA Medical Center
New Orleans, LA 70146

In section **III. Total Joint Replacement and Other Orthopaedic Implants, A. General**:
- Orthopaedic Implant Retrieval and Analysis.

In section **III., B. Hip**:
- The Mechanical Properties of Porous Coated Orthopaedic Alloy.

In section **VI. Biomechanics, E. Other**:
- A Model to Study the Mechanical Behavior of Osteoporotic Bone.

VA Medical Center
Togus, ME 04330

In section **IV. Spinal Cord Injury, I. Functional Electrical Stimulation, 1. General**:
- Computer-Controlled 22-Channel Neural Stimulator for Functional Electrical Stimulation.

VA Medical Center
Baltimore, MD 21218

In section **IV. Spinal Cord Injury, B. Medical Treatment**:
- Devices for Female Urine Incontinence.

VA Medical Center
West Roxbury, MA 02132

In section **III. Total Joint Replacement and Other Orthopaedic Implants, C. Knee**:
- A Motion-Guiding Load-Bearing External Frame for the Knee; and
- Investigation of a Simplified Internal Knee Prosthesis.

VA Medical Center
Ann Arbor, MI 48105

In section **IV. Spinal Cord Injury, I. Functional Electrical Stimulation, 4. Other**:
- Functional Electrical Stimulation for the Prevention of Pressure Sores.

VA Medical Center
St. Louis, MO 63125

In section **XIV., Head Trauma and Stroke**:
- Efficacy of Computer-Assisted Rehabilitation of Brain Injuries.

VA Medical Center
Omaha, NE 68105

In section **III. Total Joint Replacement and Other Orthopaedic Implants, A. General**:
- Orthograft Large Granular (LG) Study.

In section **III., B. Hip**:
- Porous Coated Dual-Lock Cementless Hip Clinical Investigation.

In section **III., C. Knee**:
- New Jersey Knee Clinical Investigation.

In section **VII. Wound and Fracture Healing**:
- Clinical Study: Effectiveness of EBI Bone Healing System™ in Treating Femoral Head Necrosis;
- Scientific Basis for a New Protocol in External Fixation of Fractures; and
- Electrical Osteogenesis—Mechanisms and Causes of Failure.

In section **VIII. Properties of Muscle, A. General**:
- Ethanol-Induced Cytoskeletal Dysgenesis in Muscle.

In section **XIII. Sensory Aids, A. Blindness and Low Vision, 1. General**:
- Intraocular Lens Implantation During and After Cataract Extraction.

VA Medical Center
Castle Point, NY 12511

In section **I. Amputations and Limb Prostheses, A. General**:
- A Program for Evaluation of the Dysvascular Patient

In section **IV. Spinal Cord Injury, B. Medical Treatment**:
- A Feasibility Study on Detection of Impending Pressure Sores Using Ultrasound.

In section **IV., G. Wheelchairs, Including Seating and Controls**:
- Seat Cushions for the Paralyzed.

In section **VI. Biomechanics, A. Joint Studies, 1. General**:
- Biomechanics of Bone Resorption/Regeneration at a Bone Impact Interface; and
- Stimulation of Repair of Cortical Bone Transplants by Implantation of Piezoelectric Materials: Development Study.

VA Medical Center
Cleveland, OH 44106

In section **IV. Spinal Cord Injury, I. Functional Electrical Stimulation, 2. Upper Limb Applications**:
- Functional Neuromuscular System for Upper Extremity Control.

In section **IV., I. Functional Electrical Stimulation, 3. Lower Limb Applications**:
- Walking Restored in Paralyzed Man Using Electronic Orthotics.

VA Medical Center
Dayton, OH 45428

In section **IV. Spinal Cord Injury, I. Functional Electrical Stimulation, 4. Other**:
- Fitness Improvements and Physiological Responses to FES Exercise.

VA Medical Center
Oklahoma, OK 73104

In section **IV. Spinal Cord Injury, F. Environmental Control Systems for the Severely Disabled**:
- Development of Environmental Control Units for Disabled Veterans.

VA Medical Center
Philadelphia, PA 19104

In section **I. Amputations and Limb Prostheses, B. Lower Limb, 3. Above-Knee**:
- Myoelectrically Controlled Above-Knee Prosthesis.

In section **I., C. Upper Limb, 1. General**:
- Cosmetic Covers for Upper Extremity Prostheses (Male/Female).

In section **VII. Wound and Fracture Healing**:
- Assessment of Nutritive Skin Blood Flow.

VA Medical Center
Pittsburgh, PA 15206

In section **X. Arthritis**:
- Ferrographic and Biochemical Analysis of Wear Particles in Human Joints.

In section **XIII. Sensory Aids, C. Speech Impairment**:
- Experimental Analysis of Acquisition and Generalization of Syntax.

VA Medical Center
Nashville, TN 37203

In section **VI. Biomechanics, E. Other**:
- Bone *In Vivo* and *In Vitro* Stress and Strain Patterns: Influence of Age and Activity.

In section **IX. Ligaments and Tendons**:
- Pathokinesiology of Anterior Cruciate Ligament Deficiency.

VA Medical Center
Dallas, TX 75216

In section **VII. Wound and Fracture Healing**:
- Noninvasive Quantification of Fracture Healing.

VA Medical Center
Houston, TX 77211

In section **I. Amputations and Limb Prostheses, B. Lower Limb, 1. General**:
- Automated Fabrication of Lower Extremity Prosthetic Sockets

VA Medical Center
Temple, TX 76501

In section **XIII. Sensory Aids, B. Deafness and Hearing Impairment**:
- Development of Materials for Computer-Assisted Instruction in Lipreading; and
- Development of a Digital Hearing Aid and Fitting Procedure.

VA Medical Center
Waco, TX 76703

In section **IV. Spinal Cord Injury, B. Medical Treatment**:
- The Biofeedback Incontinence Training Program.

VA Medical Center
Salt Lake City, UT 84148

In section **III. Total Joint Replacement and Other Orthopaedic Implants, B. Hip**:
- Skeletal Aging and Disease in Failure of Hip Surface Replacement.

In section **IV. Spinal Cord Injury, I. Functional Electrical Stimulation, 3. Lower Limb Applications**:
- Sensory Nerve Stimulation for Improved Neuromuscular Control.

In section **VI. Biomechanics, A. Joint Studies, 2. Lower Limb**:
- Mechanical Function of the Repaired Meniscus; and
- Biomechanical Comparison of Total Elbow Replacement Prostheses.

VA Medical Center
Richmond, VA 23249

In section **IV. Spinal Cord Injury, G. Wheelchairs, Including Seating and Controls**:
- Development of Wheelchair Standards.

VA Medical Center
Seattle, WA 98108

In section **I. Amputations and Limb Prostheses, B. Lower Limb, 1. General**:
- Predictive Value of Transcutaneous PO_2 in Peripheral Vascular Disease.

In section **III. Total Joint Replacement and Other Orthopaedic Implants**:
- Evaluation of Total Joint Loosening Using X-Ray Photogammetry.

In section **IV. Spinal Cord Injury, B. Medical Treatment**:
- The Spasticity of Spinal Cord Injury.

In section **IV., H. Personal Licensed Vehicles**:
- The Unistik Vehicle Controller: A Unique Approach to Driving for Severely Handicapped Individuals.

Clement J. Zablocki VA Medical Center
Milwaukee, WI 53193

In section **XIII. Sensory Aids, A. Blindness and Low Vision 1. General**:
- Sensory Substitution.

VA Outpatient Clinic
Boston, MA 02108

In section **XIII. Sensory Aids, B. Deafness and Hearing Impairment**:
- Direct Measurement of Loudness Recruitment in Hearing-Impaired Veterans.

VA Hospital

Little Rock, AR 72205

In section **IV. Spinal Cord Injury, B. Medical Treatment**:
- Development of Analytical and Laboratory Models of the Bladder and Urinary Tract.

In section **XV. Miscellaneous**:
- IPA Radiology.

VA Medical Center, Rehabilitation Medicine Service

Long Beach, CA 90822

In section **XV. Miscellaneous**:
- Nerve Conduction Velocity Study of the Palmar Cutaneous Branch of the Medical Nerve; and
- Serial Short Segment Stimulations (Itching) of Ulnar Nerve at the Elbow in Normal Subjects and in Neuropathy.

VA Medical Center

St. Cloud, MN 56301

In section **XIII. Sensory Aids, A. Blindness and Low Vision, 1. General**:
- Visual Field Limitation in the Patient with Dementia of the Alzheimers Type.

VA Medical Center

Manchester, NH 03104

In section **VI. Biomechanics, D. Upper Limb Function** :
- Shoulder Stabilization, The Spinal Accessory Nerve and the Trapezius Muscle.

VA Medical Center and State University of New York at Albany

Albany, NY 12208

In section **X. Arthritis**:

- Biofeedback and Relaxation Training as an Adjunctive Treatment for Severe Rheumatoid Arthritis: A Preliminary Investigation; and
- The Use of Biofeedback in the Adjunctive Treatment of Rheumatoid Arthritis: Components of Change and Underlying Psychophysiological Processes.

In section **XV. Miscellaneous**:

- Evaluation of a Comprehensive Cardiac Rehabilitation Program: Treatment Effectiveness and Long-Term Programmatic Outcome.

Wichita Rehabilitation Engineering Center

Wichita, KS 67208

John F. Jonas, Jr.; John H. Leslie, Jr.; and Roy H. Norris, Co-Directors

The Wichita Rehabilitation Engineering Center is a collaborative effort of the **Cerebral Palsy Research Foundation of Kansas, Inc.** and the **College of Engineering at Wichita State University**. In section **IV. Spinal Cord Injury, F. Environmental Control Systems for the Severely Disabled**:

- Investigation of the Utilization of a Robotic Arm by Disabled Persons in the Workplace.

Other Rehabilitation R&D Resources

Swedish Central Committee for Rehabilitation

Box 303
S-161 26 Bromma, Sweden

Mette Granstrom, National Secretary

The Swedish Central Committee for Rehabilitation (SVCR) has nine members consisting of organizations of disabled persons and acts primarily as a trust foundation. The activities of SVCR are to: promote investigative work and scientific research with a view towards preventing or restricting the effects of a disability; support measures aiming at improving or facilitating living conditions for disabled people; promote contacts with bodies active in the field of rehabilitation in other countries; and, promote the care and treatment of disabled people who need it.

The Nordic Committee on Disability

Box 303
S-161 26 Bromma, Sweden

Finn Petren, Director

The Nordic Committee on Disability is a coordinating and joint cooperative body under the Nordic Council of Ministers (the governments of the Nordic countries). The participating countries are Denmark, Finland, Iceland, Norway, and Sweden. The Committee works to promote cooperation between the Nordic countries on matters relating to disability and rehabilitation. A survey published in English reports on over 300 current research projects compiled by

the Committee. The projects cover 10 general areas: aurally handicapped, deaf; visually handicapped, deafblind; physically handicapped, including mobility aids, orthoses and prostheses, domestic aids, communication aids, and treatment, including physical therapy and medical aspects; speech handicaps; medical disabilities; mental retardation; adaptation of aids and needs analyses; housing, community planning, and public transportation; work environment; and miscellaneous.

Royal Ottawa Regional Rehabilitation Centre, Rehabilitation Engineering Department

Ottawa, Ontario, K1H 8M2, Canada

Michael D. O'Riain, Ph.D., Director of Rehabilitation Engineering

The Rehabilitation Engineering Department of the Royal Ottawa Regional Rehabilitation Centre (RORRC) is a teaching facility of the University of Ottawa. In addition to its inpatient facilities and its extensive outpatient services, the centre is involved in the coordination, administration, and planning of rehabilitation programs on a regional basis. Services provided by RORRC fall into three main categories: the operation of specialized diagnostic services; research, development, and construction of innovative aids for handicapped persons; and performance of investigative research. Over the past year, research projects have focused on: "A Wheelchair Brake Alarm," "A Silicone Condum for Urinary Drainage," "An Above-Elbow Prosthesis Employing Programmed Linkages," "A Microprocessor-Controlled Electric Feeder," and "New Foot Switches for Gait Analysis." Work on these projects has been supported by the Royal Ottawa Hospital, the Kinnear Foundation, and the Natural Sciences and Engineering Research Council, Canada.

National Research and Development Programs for Medical and Welfare Apparatus, Technology Research Association of Medical and Welfare Apparatus

3-5-8 Shibakohen, Minato-ku, Tokyo, 105, Japan

The National Research and Development Program for Medical and Welfare Apparatus is a system in which the Japanese government provides subsidies to those organizations that are qualified to develop apparatus needed in the areas of medical and welfare service. Developmental work is entrusted to the Technology Research Association of Medical and Welfare Apparatus, founded in 1976 for this purpose. Members of the association share the work among them. Medical and welfare apparatus that are manufactured as the result of this program are in use at hospitals and welfare facilities throughout Japan. Medical apparatus includes: a liver function support device; a system for early detection and treatment of neurological and psychological disorders; a removal system for immuno-related diseases; a phototechemical reaction system for diagnosis and therapy of cancer; a position computed tomography; a laser scalpel; a portable artificial kidney; an artificial heart for clinical use; a multichannel automated biochemical analyzer; and an automated differential blood-cell analyzer. Welfare apparatus includes: a substitute device for an amputated lower limb; an active artificial leg; a three-dimensional working

chair; a book-reader for the blind; a transfer supporting system for the handicapped; an automatic body temperature adjuster; a guide device for the blind; a vocal and speech training device; a middle ear implant; a module type motorized wheelchair; a braille duplicating system; a gait pattern analyzer for the handicapped; and a multifunctional bed for the bedridden.

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